



## DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

### Doctorate in Clinical Psychology: Main Research Portfolio

**1) Overgeneral autobiographical memory and depressive symptoms in older adults: An evaluative review; 2) An evaluation of psychological service provision in a palliative care setting ; 3) Psychological factors associated with selfreported sleep disturbance in Chronic Fatigue Syndrome and Insomnia**

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# Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

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Doctorate in Clinical Psychology

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June 2015

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## Abstracts

### **Literature Review: Overgeneral autobiographical memory and depressive symptoms in older adults: An evaluative review**

**Objectives:** Overgeneral autobiographical memory (OGM) is a well-researched phenomenon in adults with clinical depression. However, the nature and mechanisms of OGM have not been well established in older adults. The aim of this review was to synthesise existing literature on OGM and depressive symptoms in older adults under the framework of the *Capture and Rumination, Functional Avoidance and Impaired Executive Control* (CaR-FA-X) model (Williams, 2006; Williams et al., 2007). **Method:** Literature searches were conducted using PsychINFO, PubMed and Web of Knowledge, with search terms 1) older adults, 2) depression, and 3) overgeneral memory. Eighteen articles were reviewed. Articles were grouped into four categories by design: studies comparing healthy older and younger adults; studies comparing older adults with and without depression; longitudinal research; and intervention studies. **Results:** The literature suggests that OGM is elevated in healthy older adults compared to younger adults, and further elevated in older adults with depression. Evidence supports the role of impaired executive function as a mechanism for OGM in older adults with depression, but no studies had measured other factors implicated by the CaR-FA-X model (i.e. functional avoidance and rumination). Some support was found for the use of Life Review interventions to increase memory specificity and improve wellbeing. **Conclusion:** OGM appears prevalent in older adults with depression, however we do not yet have a clear understanding of the mechanisms through which this occurs. It is recommended that future research looks at the role of functional avoidance and rumination, and at the use of memory specificity interventions being developed in the working age adult literature.

### **Service Improvement Project: An evaluation of psychological service provision in a palliative care setting**

**Objectives:** Current UK guidelines recommend a four-level model of psychological service provision in oncology settings. This model gives responsibilities to non-psychologist professionals to provide psychological support, and places Clinical

Psychologists in a central role to provide supervision, consultation and training to other staff as well as direct clinical work. The aims of this project were: 1) to evaluate psychological service provision at a palliative care service from the perspective of staff members, and 2) to explore staff perceptions of the role of Clinical Psychology in palliative care. **Method:** Hospice staff members (n=28) completed a survey about their confidence in providing psychological support and perceived barriers to this, and providing feedback on the Clinical Psychology service. Follow-up interviews (n=2) and a focus group (n=5) were conducted to further explore staff confidence, responsibilities, and the role of Clinical Psychology. **Results:** The survey data indicated generally high levels of confidence in providing psychological support. A lack of access to recommended training, a lack of information about psychological support, and competing pressures were identified as barriers. Staff gave positive feedback on the supervision, consultation and training provided by the Clinical Psychologist, but highlighted a need for more Clinical Psychology hours. Thematic analysis on the interview and focus group data identified themes related to staff confidence, collective responsibilities, the importance of multiple perspectives, and the role and presence of Clinical Psychology. **Outcome:** The findings suggested areas for improvement and potential barriers to providing psychological support at the palliative care service. A report and recommendations were fed back to the service and plans were made to act on these. Wider implications are discussed in relation to implementing the recommended model of psychological service provision, and regarding the role of Clinical Psychology in palliative care settings.

### **Main Research Project: Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome and Insomnia**

**Objectives:** Reports of tiredness and poor quality sleep are common to both Chronic Fatigue Syndrome (CFS) and insomnia, despite evidence that sleep structure is not objectively impaired in these groups. Similar vulnerability and maintenance factors have been identified in both conditions, such as perfectionism, unhelpful beliefs and misattributions about symptoms. The aim of this study was to compare CFS and insomnia groups in terms of subjective sleep and fatigue symptoms and associated cognitive factors. **Method:** Using a cross-sectional design, CFS patients (n=18), community insomnia participants (n=18) and healthy community controls (n=19) were

compared on a range of self-report questionnaires, including measures of psychological wellbeing (depression, anxiety, worry), insomnia, sleepiness and fatigue severity, cognitions about sleep and fatigue, and other cognitive variables associated with CFS and insomnia. **Results:** Between-group analyses identified that CFS and Insomnia participants did not differ significantly on the majority of variables. Compared to controls, both groups reported poorer psychological wellbeing and higher levels of insomnia, sleepiness, and sleep-related cognitions. Both groups also reported elevated perfectionism and unhelpful beliefs about emotions. Compared to the Insomnia group, CFS participants reported higher levels of fatigue, fatigue-related cognitions, and pre-sleep somatic experiences. **Conclusions:** This study found similarities between CFS and insomnia participants in terms of cognitive processes known to maintain insomnia. This indicates that it may be appropriate to use a transdiagnostic cognitive-behavioural approach to treating sleep disturbance in CFS. The results also indicate the importance of assessing for unhelpful fatigue-related beliefs and pre-sleep somatic complaints when working with the CFS population. Implications for further research are discussed.



**University of Bath**  
**Doctorate in Clinical Psychology**

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**Literature Review**

**Overgeneral autobiographical memory and  
depressive symptoms in older adults: An  
evaluative review**

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**Intended Journal:** *Aging and Mental Health*. This peer-reviewed journal accepts submissions of review articles that summarize emerging trends, or address overlooked areas in the field of mental health and aging.

## 1. Introduction

Autobiographical memory is the sub-system of episodic memory that relates to personal experiences. The ‘self-memory system’ model, proposed by Conway and Pleydell-Pearce (2000), describes autobiographical memories as transitory mental constructions of autobiographical knowledge, which are formed either as a response to cues from the environment or as a result of conscious retrieval. The ability to ‘look back’ at one’s life history using autobiographical memory is thought to serve various functions in relation to well-being, including: forming a sense of identity and growth over time; maintaining social relationships; and learning from past experiences to guide present behaviour (see Bluck, Alea, & Ali, 2014). As noted by Bluck et al. (2014), reflecting on past events is seen as particularly important and meaningful in later stages of life.

### *1.1. Autobiographical Memory and Depression*

Depression affects around 11% of people aged 16 to 74 at any one time in the UK (Singleton, Bumpstead, O'Brien, Lee, & Meltzer, 2001). There is strong evidence that the ability to recall events from one’s past is compromised in people with depression and that this impairment can maintain depressive symptoms. Dalgleish and Werner-Seidler (2014) summarise four ways in which autobiographic memory problems contribute to depression. First, there is evidence of a bias towards recalling negative events, which reinforces a pervasive negative view of the self, other people and the world. Correspondingly, the second feature is a diminished ability to access positive memories, and a tendency to recall positive events in less detail. Third, people with depression are found to recall personal events in an ‘overgeneral’ way; memories are grouped into themes and ‘chapters’ rather than being recalled as individual events. This ‘overgeneral memory’ (OGM) effect is the main focus of the current review and is described further below. Finally, there are differences in the way people with depression relate to their autobiographical memories. For example, distressing memories may be avoided through suppression, which can lead to intrusive recall. Alternatively, negative events may be ruminated upon, reinforcing negative ideas about the self and lowered mood.

### *1.2. Overgeneral Memory*

Autobiographical memory is thought to have different degrees of specificity. Conway and Pleydell-Pearce (2000) propose a three-level hierarchical structure to the

organisation of autobiographical memories. At the broadest level, memories contain general knowledge about extended lifetime periods, for example “*when I was at primary school*”. They then contain knowledge relating to a general category of events, for example “*on school sports days*”. Finally, specific autobiographical memories contain event-specific knowledge about a single incident, for example “*winning the 100-metre race when I was eleven*”. In order to consciously retrieve a specific memory, the relevant lifetime period must first be accessed, which provides cues to access the category of events, which in turn cues retrieval of specific incidents (Conway & Pleydell-Pearce, 2000).

First described by Williams and Broadbent (1986), OGM is the tendency to retrieve autobiographical information at the general, rather than specific level. Using their Autobiographical Memory Test (AMT), Williams and Broadbent (1986) asked participants to retrieve specific autobiographical memories in response to ‘positive’ (e.g. happy, successful) and ‘negative’ (e.g. angry, lonely) cue words. They found that, compared to controls, participants who had recently attempted suicide had difficulty retrieving specific memories. The OGM phenomenon has been extensively researched since this discovery and is associated strongly with depression, as well as trauma-related disorders (for reviews, see: Sumner, 2012; Williams, 2006; Williams et al., 2007).

### *1.3. Overgeneral Memory and Depression*

The relationship between depression and OGM is well established; adults with clinical depression have difficulty generating specific memories as compared to non-depressed controls (e.g. Kuyken & Dalgleish, 1995). The effect of depressed mood on specificity has been found even when controlling for potential mediating factors, such as impaired executive function (Dalgleish et al., 2007). OGM has been identified as a trait marker for depression, as it is found to remain stable on remission and to indicate vulnerability to ongoing depression (Brittlebank, Scott, Williams, & Ferrier, 1993). A meta-analysis of studies looking at OGM as a predictor of the course of depression found that high OGM at baseline predicts higher depression symptoms at follow up; this effect occurs over and above the predictive value of baseline symptom severity (Sumner, Griffith, & Mineka, 2010).

#### 1.4. *CaR-FA-X Model*

The most comprehensive theory of the mechanisms underlying OGM is the *Capture and Rumination, Functional Avoidance and Impaired Executive Control*, or CaR-FA-X, model (Williams, 2006; Williams et al., 2007). This suggests there are three processes that contribute, on their own or in combination, to the occurrence of OGM. First, if a memory cue is associated with negative meanings about the self, the individual may get ‘captured’ by this negative self-relevant idea and begin to ruminate, disrupting the memory search. Second, OGM may represent a functional avoidance of specific memories as a way of regulating emotions; this may start as avoidance of the negative affect associated with particular (e.g. trauma-related) memories, then become a generalised retrieval style. Finally, reduced executive function capacity may contribute to OGM by making it difficult to maintain attention and inhibit inappropriate responses. Any of these mechanisms may result in the memory search being truncated at the general level, before a specific event has been identified (Williams et al., 2007).

In a comprehensive review, Sumner (2012) synthesised the evidence for the three mechanisms of the CaR-FA-X model. Strong support was found for the link between rumination and OGM, in people with depression (Crane, Barnhofer, Visser, Nightingale, & Williams, 2007) and non-clinical populations (e.g. Raes, Watkins, Williams, & Hermans, 2008; Sutherland & Bryant, 2007). Rumination is a form of ‘repetitive thinking’, which can be either constructive or unconstructive, depending on: 1) the emotional valence of the thoughts; 2) the context and situation; and 3) whether the thinking is abstract or concrete (Watkins, 2008). Rumination is hypothesised to lead to distress when the valence is negative, the context is negative, and the level of processing is abstract. In line with this model, ruminating on negatively-valenced information and thinking in an abstract, analytical way have been identified as related to OGM (Sumner, 2012). Evidence for the ‘capture’ mechanism appears more mixed. Self-relevant cues have been found to trigger OGM in individuals with a history of depression (e.g. Crane, Barnhofer, Mark, & Williams, 2007; Spinhoven et al., 2007); however the opposite effect – *increased* memory specificity – has been found in a non-clinical population (Sumner, Griffith, & Mineka, 2011). Sumner therefore suggests that ‘capture’ may only occur in the presence of negative self-schemas.

Reasonable evidence has been found for OGM as a functional avoidance strategy, particularly in Post-Traumatic Stress Disorder (PTSD), although Sumner (2012) highlights a need for longitudinal research into how this mechanism develops. The

functional avoidance aspect may depend on whether OGM is defined as high memory generality, or low memory specificity. Retrieving low numbers of specific memories appears to protect against negative emotions following an aversive experience, whereas retrieving high numbers of overgeneral memories appears to *increase* distress (Raes, Hermans, Williams, & Eelen, 2006). This suggests it may be avoidance of negative specific memories that serves an affect regulation function, as opposed to OGM per se (Sumner, 2012).

In further support of the CaR-FA-X model, there is robust evidence for the relationship between impaired executive control and OGM (Sumner, 2012). Various aspects of executive functioning have been implicated in OGM, including impaired inhibition and updating abilities (Piolino et al., 2010) and reduced working memory capacity (e.g. Neshat-Doost, Dalgleish, & Golden, 2008). Impaired executive control has been found to influence OGM in adults with depression independently of the effect of depressed mood (Dalgleish et al., 2007).

The CaR-FA-X model is well supported, however it is not proposed as a “one size fits all” model (Crane, Barnhofer, Visser, et al., 2007; Sumner, 2012). The different mechanisms operate independently and may make different contributions to OGM in different populations. Understanding the particular mechanisms underlying OGM in different populations is important in order to develop tailored methods of intervention as research in this field progresses (Sumner, 2012).

### *1.5. Older Adults*

Older people are particularly vulnerable to depression, with around one in four people over 65 experiencing depression at any one time (Craig & Mindell, 2005). Understanding and addressing factors associated with depression is therefore an important priority in this population. There are a number of reasons to assert that the nature of the relationship between OGM and depression may be different in older adults compared to adults of working age. Firstly, even in healthy aging, there are known declines in executive functions such as working memory, filtering information, and metacognitive control (MacPherson, Phillips, & Della Sala, 2002; Salthouse, Atkinson, & Berish, 2003; Souchay & Isingrini, 2004; Zanto, Hennigan, Östberg, Clapp, & Gazzaley, 2010). Older adults with depression have more significant executive function impairments than non-depressed older adults (Lockwood, Alexopoulos, & van Gorp,

2002). Given the established relationship between executive function and OGM, this is likely to be significant.

Secondly, research indicates there are differences in the nature of autobiographical memory in healthy older adults compared to younger adults. When asked to recall different life periods, older adults show a bias towards semantic descriptions (of meanings and knowledge) that are not linked to a particular place or time, whereas younger adults provide more episodic details (Levine, Svoboda, Hay, Winocur, & Moscovitch, 2002). When asked to freely recall life events, older adults tend to retrieve more memories from adolescence and early adulthood than later life periods, and show more positive associations with this time period; this phenomenon is known as the ‘reminiscence bump’ and is hypothesised to be due to the high frequency of formative events occurring during early life (Rubin, Rahhal, & Poon, 1998). It has been suggested that over time, autobiographical memories become more integrated into a personal life narrative with an emphasis on meaning, rather than episodic details (Levine, 2004). These effects of aging on autobiographical memory may result in older adults naturally retrieving more memories at the ‘general’ level on tasks such as the AMT. It could also be hypothesised that OGM would be less prominent in older adults when asked to recall events from the ‘reminiscence bump’, due to the salience and meaning of events in younger life.

Finally, there are frequent findings of a ‘positivity bias’ in older adults (see Carstensen et al., 2011). Despite the prevalence of depression in this group, aging is commonly associated with more positive emotional well-being and stability. It has been suggested that this occurs due to attentional and memory biases towards positively-valenced information as a means of emotion regulation (Mather & Carstensen, 2005). Older adults also retrieve more positive autobiographical memories compared to younger adults (Kennedy, Mather, & Carstensen, 2004), although this effect is diminished in older adults with depression (Yang & Rehm, 1993). The positivity bias may have an influence on the nature of OGM in response to different types of memory cues (positive or negative).

### *1.6. Treatment*

It is becoming important to establish the nature of OGM in older adults with depression so that they can benefit from advances in treatment that are being developed in the OGM literature (see Dalgleish & Werner-Seidler, 2014). Interventions aimed at

increasing autobiographical recall and specificity, such as Method-of-Loci and Memory Specificity Training (MEST), are showing promising outcomes in working age adults with depression. Method-of-Loci involves asking individuals to rehearse retrieval of positive memories using a mnemonic technique that links the memories with locations on familiar journeys. This technique has been found to improve access to specific positive memories in people with depression (Dalgleish et al., 2013). Trials of MEST, a group-based programme in which participants practice retrieving specific memories, have demonstrated positive outcomes in individuals with depression in terms of improving memory specificity and reducing depressive symptoms (Neshat-Doost et al., 2013; Raes, Williams, & Hermans, 2009).

To know whether the above techniques and interventions can be equally applied to helping older adults with depression, we first need to understand OGM in older adults.

### *1.7. Current Review*

There has been increasing research into OGM in older adults. This has included studies looking at differences between healthy older and younger adults, specific clinical groups (e.g. people with depression or dementia) and interventions for increasing memory specificity. The purpose of this evaluative review is to establish what is currently known about OGM in relation to depression in older adults, as a synthesis and to guide future research. Key questions that the review aims to address are: whether there are differences in OGM between older and younger adults in the absence of depression; whether OGM is a characteristic feature and relapse marker of depression in older adults as it is in working age adults; and whether interventions targeted at increasing memory specificity can be effective for treating depression in older adults. The existing research findings are considered under the theoretical framework of the CaR-Fa-X model, and the potential clinical implications are discussed.

## **2. Method**

Literature searches were conducted in January 2015 using PsychNET, PubMed and Web of Knowledge (Science Citation Index and Social Science Citation Index). Three search terms and possible synonyms were used: 1. Older Adults (old age, elderly, geriatric, gerontology), 2. Depression (depressive, mood disorder, low mood, dysthymia, anhedonia), and 3. Overgeneral Memory (autobiographical memory, OGM). The date was restricted to articles published from 1986 onwards, following Williams

and Broadbent's (1986) original article describing OGM. Book chapters and unpublished dissertations were not included.

The search returned 253 references after removal of duplicates. Titles and abstracts were then reviewed to screen against the following inclusion criteria: 1. Published in the English language (9 excluded), 2. Described peer-reviewed, original research (24 excluded), 3. Focused on an older adult population, defined broadly for the purpose of this review as aged 50 and above (133 excluded), 4. Did not focus on older adults with cognitive impairment or medical/psychiatric diagnoses apart from depression (25 excluded), 5. Employed a standardised measure of depression, which was not used solely for the purpose of screening out participants (20 excluded), and 6. Employed a quantitative measure of OGM or autobiographical memory specificity (24 excluded). If any criteria were unclear from the title and abstract, articles were accessed in full to assess eligibility. References from included articles were examined for relevant papers, which resulted in a further 5 articles being screened for eligibility; these were all excluded due to an absence of depression measures. Eighteen articles were included for full review and broadly categorised into four groups based on design:

- Non-clinical cross-sectional studies comparing older adults (OA) and younger adults (YA)
- Cross-sectional studies comparing OA with and without depression symptoms (non-clinical samples), or clinical depression (clinical samples).
- Longitudinal studies
- Intervention studies

The design, sample and measures used in the included studies are summarised in **Tables 1-5**. In addition to reviewing the content, the quality of each study was considered using the checklist in **Appendix A**. This checklist was taken from one used by the journal *Behavioural and Cognitive Psychotherapy* as part of their peer-review process, and was used as a guide for critically appraising the design, methodology and clarity of each article.



### 3. Results

#### *3.1. Non-Clinical Cross-Sectional Studies comparing Older Adults with Younger Adults (see Table 1)*

A number of studies compared OGM in healthy OA and YA, while effectively controlling for depression symptoms. These are included in the current review as they provide relevant information about differences in OGM between older and younger adults in the absence of depression.

Two studies examined the relationship between OGM and executive function. Ros et al. (2010) found that OA performed worse than YA on tasks of working memory and sustained attention, and retrieved fewer specific and more categorical memories on the AMT. Structural equation modelling using data from both age groups showed that better working memory contributed to improved memory specificity. The authors therefore conclude that the cognitive changes associated with aging account for OGM in OA (Ros et al., 2010). However, many of the executive function tasks employed in this study were not well-recognised or validated measures. The description of the administration of the AMT also suggests that these authors did not provide participants with prompts when they retrieved a general memory, which would have negatively impacted on scores and limits comparison with other studies. Findings from Holland et al. (2012) were not as conclusive. These authors looked at the relationship between memory specificity on the AMT and two aspects of executive control: updating (altering responses based on working memory of previous responses) and inhibition (inhibiting inappropriate responses). OA showed poorer executive functioning than YA and recalled fewer specific memories in response to neutrally-valenced cues. Across both groups, better updating predicted greater memory specificity. These findings support the role of executive functioning in OGM, specifically the ‘updating’ aspect of working memory. However, OGM was only found in OA in response to neutral cues: no difference in memory specificity was found between age groups for positive or negative cues. This suggests a preserved ability to retrieve specific memories with stronger emotional associations. Holland et al. (2012) suggest that such memories require less cognitive effort to retrieve, compensating for age-related declines in executive function.

Executive control has also been looked at in relation to the ability to follow task instructions. Ford et al. (2014) used a musical-cued version of the AMT to examine the

**Table 1:** *Non-Clinical Cross-Sectional Studies- Older Adults vs Younger Adults*

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Ford, Rubin, and Giovanello (2014)	USA	1. YA (N=25)  2. OA (N=21), within subjects	1. 10 male, 15 female  2. 10 male, 11 female	1. M= 18.7, SD= 0.76,  2. M= 75.6, SD= 5.97	Beck Depression Inventory (BDI): Used to check group equivalence	Novel musical cue task	Executive function tasks: Stroop, N-back, Number-Letter switching
Holland, Ridout, Walford, and Geraghty (2012)	UK	1. YA (N=25)  2. OA (N=21)	Not available	1. 18-35, M=21.6, SD= 4.65  2. 55-87, M=69.52, SD= 10.52	Hospital Anxiety and Depression Scale (HADS): Used to compare groups and controlled for in analyses	AMT	Random Number Generation (measures of inhibition and updating)
Martinelli, Anssens, Sperduti, and Piolino (2013)	France	1. YA (N=18)  2. OA (N=16)  3. OA with dementia (N=10)	1. 8 male, 10 female  2. 6 male, 10 female  3. 1 male, 9 female	1. M= 22.16, SD= 1.92  2. M= 75.18, SD= 4.61  3. M= 76.30, SD= 4.01	BDI: Used to exclude if score 14+, and entered as covariate in analyses.	Word cued recall of 'autobiographical episodes', 'personal semantics' and 'self-defining memories'	Tennessee Self-Concept Scale

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Ros and Latorre (2010)	Spain	1. YA (N=50)  2. OA (N=46)	1. 21 male, 29 female  2. 11 male, 35 female	1. 23-30, M=26.59, SD=2.07  2. 57-80, M=65.98, SD=5.54	Center for Epidemiological Studies-Depression scale (CES-D): Used as covariate in analyses	AMT (valence only reported)	None
Ros, Latorre, and Serrano (2010)	Spain	As above	As above	As above	As above	AMT	Measures of Working Memory, Short Term Memory and Sustained Attention

impact of manipulating task instructions on OGM. Their OA and YA groups were equivalent in depression symptoms and executive function performance. Task instructions were varied so that participants were asked to recall 1) specific, 2) general, or 3) any memory. Across all conditions, OA retrieved fewer memories, a smaller proportion of specific memories and less memory detail compared to YA. Notably, OA recalled the same proportion of specific memories *regardless* of task instruction, whereas YA modified their responses, recalling more specific memories in the ‘specific’ condition. This suggests that OA have difficulty implementing task instructions, even in the absence of observable executive function deficits or depression. Ford et al. (2014) also suggest that OA have a natural bias towards OGM due to an age-related tendency to incorporate events into an overall life narrative, as proposed by Levine (2004). The novel musical-cued AMT used in this study was selected due to evidence that music is particularly effective for the retrieval of salient memories. However, this limits the generalisability of Ford et al.’s (2014) findings, as it is not clear whether the same retrieval processes are involved in response to visual or verbal cues. Replication with the standard verbal AMT would enable firmer conclusions and comparison with other studies.

In a study stemming from literature on self-concept, Martinelli et al. (2013) compared YA with healthy OA and OA with dementia on a novel word-cue memory task. ‘Autobiographical episodes’ (specific memories), ‘personal semantics’ (general knowledge about the self) and ‘self-defining memories’ (episodic memories related to self-concept) were recorded. Healthy OA recalled fewer specific memories than YA, however retrieval of specific ‘self-defining’ memories did not differ. This suggests that, despite deterioration in memory specificity, healthy OA have a preserved ability to retrieve memories at the specific episodic level when they are highly self-relevant. Consistent with the ‘positivity bias’, Martinelli et al. (2013) also found that healthy OA produced more positive ‘personal semantics’ than YA, and that having a positive self-concept was associated with more positive ‘personal semantics’ and ‘self-defining’ memories. In further support of the ‘positivity bias’, Ros and Latorre (2010) found that healthy OA retrieved fewer negative memories in response to negative cues than YA. These findings support the idea that reduced memory specificity for negative events might be associated with better wellbeing, as suggested by Raes et al. (2006).

### *3.2. Cross-Sectional Studies comparing Older Adults with and without Depression Symptoms*

To address the question of whether OGM is a characteristic feature of depression in older adults as it is in younger adults, cross-sectional studies comparing older adults with and without depression symptoms were reviewed. These included studies that employed non-clinical samples (i.e. older adults with high scores on depression measures but without a clinical diagnosis), as well as clinical samples.

#### **3.2.1. Non-Clinical Samples (see **Table 2**)**

Two studies (Latorre et al., 2013; Serrano et al., 2007) were conducted by the same research group. Serrano et al. (2007) found that OA with depression symptoms recalled more general memories than those without, but only for negative cues. There was no difference in specific memory recall. This indicates that the presence of OGM in OA with depression symptoms may be specific to negative memories, and occur due to increased generality rather than reduced specificity. The authors attribute this to rumination truncating the memory search at the general level. This is in line with findings that increased memory generality is associated with distress (Raes et al., 2006). Both groups showed a bias towards positive memories. However, those with depression symptoms retrieved significantly more negative memories than those without, suggesting that depression is associated with a less pronounced ‘positivity bias’. Consistent with Serrano et al. (2007), Latorre et al. (2013) found that OA with high and low depression symptoms recalled more positive than negative memories. Both their groups were also slower to recall negative than positive memories. This further supports the ‘positivity bias’ and may indicate functional avoidance of specific negative memories. In contrast to Serrano et al. (2007), Latorre et al. (2013)’s high depression group produced fewer specific memories than the low depression group, with no significant difference in general memory retrieval, indicating OGM through reduced specificity rather than increased generality. Although no relationship was found between depression scores and OGM, higher life satisfaction was associated with higher memory specificity. The authors therefore propose that high memory specificity may be protective against depression. A limitation of both Serrano et al. (2007) and Latorre et al. (2013), as well as other studies conducted by this research group, is that they altered administration of the AMT by not prompting participants who initially recalled a

**Table 2:** Cross-Sectional Studies- Older Adults with/without Depression Symptoms (Non-Clinical Populations)

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Gidron and Alon (2007)	Israel	OA (N=25)	12 male, 13 female	65-89, M=77.92, SD=6.5	Geriatric Depression Scale-15 items (GDS-15): Cut-off 7 for inclusion	AMT, adapted to cue for life periods	None
Haringsma, Spinhoven, Engels, and van der Leeden (2010)	Netherlands	1. OA with remitted depression (N=63)  2. OA with no history of depression (N=60)  T1. Baseline T2. Post mood-induction.	1. 15 male, 48 female,  2. 13 male, 47 female	1. 55-86, M=64.92, SD=6.84  2. 55-86, M=64.47, SD=6.65	MINI diagnostic interview  CES-D	AMT	Visual Analogue Mood Scale
Latorre et al. (2013)	Spain	1. OA with high depression symptoms (N= 33)  2. OA with low depression symptoms (N= 33)	1. 14 male, 19 female  2. 12 male, 21 female	1. M= 72.09, SD= 7.88  2. M= 72.52, SD= 5.61	CIDI diagnostic interview  CES-D : Cut-off 16 for group allocation	AMT	Life Satisfaction Index

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Serrano, Latorre, and Gatz (2007)	Spain	1. OA with depression symptoms (N=95)  2. OA without depression symptoms (N=90)	77 male, 108 female	60+, M= 72.21, SD= 7.56	CES-D: Cut-off 16 for group allocation)	AMT	None

general memory. This would be likely to reduce the scores obtained and limits the ability to compare the findings with other studies.

To explore whether OGM is a ‘state’ or ‘trait’ marker for depression in OA, Haringsma et al. (2010) compared the AMT performance of OA with remitted depression symptoms to matched healthy OA. Participants were assessed pre and post a negative mood induction. No difference was found between groups in terms of memory specificity, and although the induction successfully induced a sad mood for both groups, the sad mood state did not influence OGM in either group. This suggests that OGM is not sensitive to current mood state in OA, nor is it a ‘trait’ marker of past depression. Haringsma et al. (2010) propose that the effects of normal ageing on OGM may override the detrimental effect of past depression, resulting in no observable difference between never-depressed and remitted-depressed OA. It is worth noting, however, that the ‘remitted depressed’ group were not a clinical sample initially, and prior to participating they had undergone an intervention for depression symptoms that included addressing rumination. Given the relationship between OGM and rumination proposed by the CaR-FA-X model, this intervention may have reduced OGM in Haringsma et al. (2010)’s sample.

In a study examining the ‘reminiscence bump’, Gidron and Alon (2007) used an adapted version of the AMT to cue for memories from different life periods. They found that specificity for memories from adolescence was negatively correlated with depression scores. OA who scored above cut-off for depression symptoms showed reduced specificity for childhood and adolescent memories compared to those below cut-off. This suggests that depression is associated with OGM for the ‘reminiscence bump’, which is commonly found to have positively-biased recall. The authors are inconclusive about reasons for this: depression may make it harder to retrieve memories from adolescence, or difficulty retrieving memories from this period may be a risk factor for depression. Alternatively, both could be associated with a common factor such as adolescent hormone levels (Gidron & Alon, 2007).

### 3.2.2. Clinical Samples (see **Table 3**)

In the earliest study identified in this review, Fromholt et al. (1995) compared OA with first episode clinical depression, OA with dementia and healthy controls, in performance on a novel memory task. Participants were asked to talk freely for 15



**Table 3: Cross-Sectional Studies- Older Adults with/without Depression (Clinical Populations)**

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Birch and Davidson (2007)	UK	1. OA with depression (N=17)  2. OA without depression (N=17)	1. 4 male, 13 female  2. 6 male, 11 female	1. 65+, M=71.5, SD=4.7  2. 65+, M=73.9, SD= 5.1	GDS-30: Cut off 14	AMT	Wechsler Memory Scale III, Working Memory Index, Mini Mental State Exam (MMSE), Wechsler Test of Adult Reading
Fromholt, Larsen, and Larsen (1995)	Denmark	1. OA with first episode depression (N=15)  2. OA with dementia (N=30)  3. Healthy OA (N=30)	1. 2 male, 13 female  2. 5 male, 25 female  3. 12 male, 18 female	1. 72-90, M=80.2, SD= 5.27  2. 73-89, M=80.5, SD= 4.36  3. 71-89, M=78.3, SD= 4.81	Clinical diagnosis according to DSM-III	Free recall narrative on “events that have been important in your life”	Brief Cognitive Rating Scale: Used to check for cognitive decline in depression group
Ricarte et al. (2011)	Spain	1. OA with depression (N=34)  2. OA without depression (N=34)	1. 5 male, 29 female  2. 7 male, 27 female	1. 65+, M= 74.59, SD=5.48  2. 65+, M=75.09, SD=7.56	MINI diagnostic interview	AMT	Life Satisfaction Index, Beck Hopelessness Scale

minutes about “events that have been important in your life”. The number of memories, valence and level of detail was scored, along with the distribution across the lifespan. OA with depression recalled fewer, less detailed memories than controls, and performed no better than OA with dementia, suggesting that depression can be as detrimental to autobiographical recall as organic cognitive impairment. The group with depression also produced significantly more memories from the recent past (during the episode of depression), and a larger proportion of negative memories for this time period than the other groups. The authors suggest that having depression may make it more difficult to retrieve earlier memories due to rumination on recent negative events. However, rumination was not measured in this study. Although interesting in terms of the effects of depressed mood on memory chronology and valence, the use of free recall and memory ‘detail’ as the only measure of specificity makes these findings difficult to compare with those from studies employing the AMT.

Two studies (Birch & Davidson, 2007; Ricarte et al., 2011) have compared AMT performance between OA with clinical depression and healthy OA controls. Birch and Davidson (2007) looked at executive function in relation to OGM. OA with depression in Secondary Care recalled fewer specific memories than controls, but there were no significant differences in the number of general memories. This suggests that there is more pronounced OGM in depressed compared to non-depressed OA, due to reduced specificity rather than increased generality. For both groups combined, a positive relationship was found between specific memories and working memory, and a negative relationship between categoric memories and working memory. However, neither age nor depression score was related to OGM. These findings support the significant role of executive functioning in OGM, over and above the influences of age and depression. Interestingly however, no difference was found between groups in terms of cognitive functioning: depressed OA recalled fewer specific memories than controls despite having preserved working memory. The authors therefore propose an added role of self-referent rumination in depression that interrupts the memory search, although rumination was not explicitly measured. Ricarte et al. (2011) found that OA with depression in Primary Care recalled fewer specific memories and more extended memories than controls. In contrast with Birch and Davidson (2007), this suggests that OGM occurs due to *both* reduced specificity and increased generality. OA with depression also showed greater OGM in response to negative than positive cues, potentially indicating a functional avoidance of specific negative memories. Finally,

Ricarte et al. (2011) found that higher memory specificity was associated with increased life satisfaction and reduced hopelessness in their control group, suggesting that memory specificity could be protective against depression.

### *3.3. Longitudinal Studies (see Table 4)*

Two of the above studies additionally included longitudinal elements to their design, which can help to address the question as to whether OGM is a marker for vulnerability to depression in OA. To establish whether OGM was predictive of depressive relapse, Haringsma et al. (2010) followed up their OA with remitted depression at 14-17 months. They found that baseline scores and responsiveness to mood induction on the AMT did not predict new depressive episodes or depression scores at follow-up. This suggests that OGM does not act as a marker for depression or predict relapse in OA, as it does in working age adults (e.g. Brittlebank et al., 1993). However, as noted above, the sample of remitted depressed OA in this study was from a non-clinical population and had previously received an intervention that may have altered OGM.

Fromholt et al. (1995) followed up their group with first episode depression at 6 months to re-assess depression and performance on the free narrative memory task. At follow up, those who had recovered from their depressive episode still tended to recall more memories from the recent past, however there was no longer a bias towards negative memories. This supports ‘state’ rather than ‘trait’ theories of the effects of depression on memory, as the negativity bias was lost on recovery. However, there was no change in the detail of the memories retrieved between baseline and follow-up, indicating that remission did not improve memory specificity and OGM could potentially be a ‘trait’ marker of depression in OA. It must be noted that the memory task administered in this study did not prompt participants for specific memories as in the AMT, therefore only limited conclusions can be made regarding OGM.

### *3.4. Intervention Studies (see Table 5)*

In order to address the question as to whether improving memory specificity can effectively treat depression in OA, studies looking at OGM in the context of interventions for depression were reviewed. The majority of these studies focused on the use of therapeutic group interventions. However, one study measured memory specificity in the context of a medication trial. Gallassi et al. (2006) assigned OA with depression to receive one of two antidepressant therapies, and compared with matched

**Table 4: Longitudinal Studies**

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Fromholt et al. (1995)	Denmark	OA with first episode depression (N=15)  T1. Baseline (as above) T2. 6m follow-up	2 male, 13 female	72-90, M= 80.2, SD= 5.27	Clinical diagnosis according to DSM-III	Free recall narrative on “events that have been important in your life”	Brief Cognitive Rating Scale
Haringsma et al. (2010)	Netherlands	OA with remitted depression (N=61)  T1. Baseline (as above) T2. 14-17m follow-up	Not available	Not available	MINI diagnostic interview  CES-D	AMT	None

**Table 5: Intervention Studies**

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
de Medeiros, Mosby, Hanley, Pedraza, and Brandt (2011)	USA	<p>OA (non-clinical)</p> <p>1. Autobiographical Writing Group (N=18)</p> <p>2. Oral Reminiscence Group (N=18)</p> <p>3. Control Group (N=15)</p> <p>T1. Baseline T2. Post-intervention T3. 26 week follow-up.</p>	<p>1. 7 male, 11 female</p> <p>2. 6 male, 12 female</p> <p>3. 7 male, 8 female</p>	<p>1. 67-88, M=79.6, SD=6.1</p> <p>2. 71-96, M=81.5, SD=5.9</p> <p>3. 73-87, M=81.1, SD=4.0</p>	GDS-15	<p>Autobiographical Memory Interview ('autobiographical incidents')</p> <p>Remote Memory Word Association Task ('episodic specificity')</p>	Hopkins Verbal Learning Test, Brief Visuospatial Memory Test, Short Form-36, NEO Five-Factor Inventory, Tennessee Self-Concept Scale
Gallassi, Di Sarro, Morreale, and Amore (2006)	Italy	<p>1. OA with depression (N=48), assigned to either a. Fluoxetine (N=24) b. Reboxetine (N=24)</p> <p>2. Matched Healthy OA (N=15).</p> <p>T1. Baseline T2. 6m of treatment</p>	<p>1. 12 male, 36 female</p> <p>2. 6 male, 9 female.</p>	<p>1. 50+, M=67.54, SD=8.08</p> <p>2. 50+, M=69.33, SD=5.49</p>	<p>Clinical Diagnosis</p> <p>Hamilton Rating Scale</p> <p>GDS-30</p>	<p>Autobiographical Memory interview (content and detail of memories)</p>	WMS, Familial/Famous Face Recognition, Attentional Matrices, Stem Completion, MLT '88 test for Historic Events.

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Goncalves, Albuquerque, and Paul (2009)	Portugal	OA with depression symptoms  1. Life Review Intervention Group (N=11)  2. Control Group (N=11)  T1. Baseline T2. Post-intervention	22 female	65+, M=80.7, SD= 4.5	GDS-15: Cut-off 4 for study inclusion	AMT	Life Satisfaction Index
Ramirez, Ortega, Chamorro, and Colmenero (2014)	Spain	OA  1. Life Review Intervention Group (N=26)  2. Placebo Group (N=20)  T1. Baseline T2. Post-intervention T3. 4m follow-up.	1. 10 male, 16 female  2. 7 male, 13 female	60-93, M=71.18, SD= 7.06	BDI	AMT	State and Trait Anxiety Inventory, Life Satisfaction Scale, Subjective Happiness Scale

Study	Location	Sample	Gender	Ages	Depression Measure	OGM Measure	Other Measures
Serrano, Latorre, Gatz, and Montanes (2004)	Spain	OA with depression symptoms  1. Life Review Intervention Group (N=20)  2. Control Group (N=23)  T1. Baseline T2. Post-intervention	10 male, 33 female	65-93, M=77.19, SD=7.68	CIDI diagnostic interview for caseness  CES-D for inclusion: Cut-off 16	AMT	Life Satisfaction Index, Beck Hopelessness Scale
Serrano Selva et al. (2012)	Spain	OA with depression  1. Life Review Intervention Group (N= 18)  2. Placebo Group (N=19)  T1. Baseline T2. Post-intervention T3. 6 week follow-up T4. 6m follow-up.	6 male, 31 female	64-83, M=73.9	MINI diagnostic interview  GDS-30	AMT	Beck Hopelessness Scale, Life Satisfaction Index, Quality of Life in Depression Scale

controls. Participants were assessed for depression symptoms and cognitive performance at baseline and at 6 months post treatment. Measures included an autobiographical memory task in which participants were asked to recall memories from different life periods. Memories were scored for content and level of detail. At baseline, OA with depression showed poorer performance on the autobiographical memory task and on working memory tasks. Following treatment, those in remission from depression showed improvements in autobiographical memory and working memory. These findings suggest that depression in OA affects various aspects of memory, including the specificity of autobiographical memory, and that much of this impairment is related to the depressed state and improves on remission. However, performance of the remitted participants remained significantly worse than controls, suggesting residual autobiographical memory problems that might indicate a depressive 'trait'. It must be noted that OGM was not the primary focus of this trial, which looked at various cognitive factors. As such, the autobiographical memory task is only briefly described and it is difficult to ascertain to what extent this provides a comparable measure of OGM.

de Medeiros et al. (2011) randomly assigned their community sample to either an autobiographical writing intervention, an oral reminiscence intervention, or an inactive control group. Participants were assessed pre and post-intervention and at 6 month follow-up using measures of autobiographical memory, depression and wellbeing. Compared to the control group, neither intervention led to significant improvements in recall for specific autobiographical incidents, memory detail, or depression score. However, while the interventions involved recalling autobiographical memories, they did not explicitly target memory specificity. Additionally, the authors note that the autobiographical memory tasks they used are usually used with people with cognitive impairment, therefore may not have been sensitive enough to detect change in a non-clinical sample (de Medeiros et al., 2011).

In a study using the AMT, Ramirez et al. (2014) allocated their OA community sample to either a Life Review intervention focused on memory specificity, gratitude and forgiveness, or a placebo group which focused on more general early life memories. Participants were assessed pre and post intervention and 4 month follow-up using the AMT, measures of depression and wellbeing. A significant reduction in depression and an increase in life satisfaction and happiness was found following the Life Review intervention, but not in the placebo group. There was also a significant increase in



specific memory retrieval in the intervention group, but not placebo group. This suggests that a Life review intervention explicitly focused on memory specificity can improve OGM and mood in OA post-intervention. However, the gains found following the intervention were not maintained at follow-up. The authors also did not explicitly look at the relationship between change in depression score and change in OGM, therefore it cannot be inferred whether the increased memory specificity led to improvements in mood. As the intervention targeted 'gratitude' and 'forgiveness' as well as memory specificity, it is not possible to separate which part was helpful.

Goncalves et al. (2009) allocated OA with depressive symptoms to either a Life Review intervention, or inactive control group. Participants were assessed pre and post intervention using the AMT and measures of depression and life satisfaction. They found that both the intervention and control groups demonstrated an increase in specific and positive memories on the AMT, however this was only significant in the intervention group. There were also greater improvements in depression & life satisfaction scores in the intervention group. This supports the use of Life Review to increase memory specificity and improve depression symptoms. However, the conclusions that can be drawn are limited due to the lack of an active control group and follow-up period. This study also employed a very small sample and does not report the demographics of the two groups separately. Further, the results section of this article was appraised as being particularly poor in quality. Only the data for significant findings are provided, meaning that the reader cannot draw conclusions regarding the magnitude of the differences between the Life Review and control groups.

The final two studies were conducted by the same research group, Serrano and colleagues. Serrano et al. (2004) allocated OA with depression symptoms to a Life Review intervention or inactive control group. Participants were assessed pre and post intervention using the AMT, depression, hopelessness and life satisfaction measures. Consistent with Goncalves et al. (2009), a significant reduction in depression and hopelessness and an increase in life satisfaction was found following intervention, but not in the control group. A significant increase in specific memories was found in the intervention group, and Serrano et al. (2004) also looked at the relationship between changes in OGM and depression scores. They found that change in memory specificity was a significant predictor of post-intervention hopelessness and life-satisfaction (and nearly significant for depression), when controlling for baseline scores. Although the

direction of the relationship cannot be concluded, this finding supports the relationship between improved memory specificity and improved mood. Serrano Selva et al. (2012) addressed methodological limitations of the group's earlier trial by employing a clinical sample, an active control of supportive therapy, and follow-ups at 6 weeks and 6 months. Participants randomised to receive the Life Review intervention did not improve any more than the control group in terms of depression score, hopelessness or life satisfaction. However, in the intervention group, there was an increase over time in specific memories and this was associated with improved depression scores. These changes were maintained on follow up. Those who produced more specific memories decreased depression scores at a faster rate, suggesting that increased memory specificity may be a mechanism for improvement in depression. Overall, the findings of Serrano and colleagues indicate that Life Review can successfully increase memory specificity and that this is associated with improvements in mood and wellbeing. However, Life Review may not be more successful than other forms of therapy at improving depression symptoms.

### *3.5. Methodological Limitations*

Some general limitations of the reviewed literature are important to note. The majority of the studies employed small sample sizes, limiting their statistical power and generalisability. The studies were variable as to whether clinical populations were used and how these were defined. In some instances, the demographics of the sample, or groups within the sample, were not fully described. Additionally, many of the studies did not state whether the mental health history of the participants was screened, therefore it cannot be known whether the sample included individuals with difficulties apart from depression (e.g. PTSD), which might influence OGM. The inclusion or exclusion of participants on antidepressant medications also varied between studies, which could contribute to variability in the findings.

It was notable that seven of the eighteen reviewed studies were published by the same Spanish research group (Serrano, Latorre, Ricarte, Ros and colleagues). Again, this limits the generalisability of the conclusions drawn as it is not clear to what extent these findings will replicate by different researchers and in different cultural groups.

Although the AMT was used to assess OGM in the majority of studies, some used other methods that limit the ability to compare findings. Among those that did use the AMT,

the exact procedure was not always clearly described, and the descriptions indicated variations in task administration. For example, some researchers did not prompt participants if they initially retrieved a general memory (e.g. Serrano and colleagues) which would likely lower memory specificity score, whereas others provided prompts and scored participants' final responses (e.g. Holland et al., 2012) which would likely increase specificity score. This variability means that it is not feasible to directly compare the data from different studies.

## **4. Discussion**

The current review aimed to establish what is currently known about OGM in relation to depression in older adults, and to identify potential clinical and research implications emerging from this field of research.

### *4.1. Older Adults and OGM*

The findings from studies comparing healthy older and younger adults provide evidence that, in the absence of depression, older adults have increased OGM compared to younger adults. The evidence also indicates that at least part of this effect is due to age-related declines in executive functioning, with both working memory (Ros et al., 2010) and 'updating' of the memory search (Holland et al., 2012) identified as possible mechanisms. This further supports the role of reduced executive function capacity in OGM, as proposed by the CaR-FA-X model (Williams, 2006; Williams et al., 2007), and suggests this element of the model is especially relevant to older adults.

Executive function problems alone cannot account for the OGM effect in older adults, however, as there are findings that OGM occurs in the absence of working memory deficits (or depression; Ford et al., 2014) and that memory specificity to emotional cues is preserved in the presence of reduced working memory (Holland et al., 2012). To account for this, Ford et al. (2014) point to a possible age-related tendency to incorporate memories into a single life narrative, leading to overgeneral recall. The retrieval of specific memories that are emotionally-valenced (Holland et al., 2012) and self-referent (Martinelli et al., 2013) appears relatively preserved in healthy older adults. Therefore, it may be that memories that are highly related to older adults' integrated self-concept are retrieved more automatically than less self-referent memories, overcoming age-related declines in executive function.

The evidence reviewed in healthy older adults is consistent with the concept of a 'positivity bias' in autobiographical memory, with findings that older adults retrieve fewer specific negative memories than younger adults (Ros & Latorre, 2010) and that a positive self-concept improves retrieval for specific positive memories (Martinelli et al., 2013). This also supports the idea that OGM in the form of reduced memory specificity to negative events might be beneficial to wellbeing (Raes et al., 2006).

#### *4.2. Older Adults, Depression and OGM*

The findings from studies comparing healthy older adults to those with clinical or non-clinical depression suggest, with one exception (Haringsma et al., 2010), that depression is associated with increased OGM in older adults as it is in working age adults. However, the literature does not agree as to whether this occurs due to increased memory generality (Serrano et al., 2007), reduced specificity (Birch & Davidson, 2007; Latorre et al., 2013), or a combination of both (Ricarte et al., 2011). In line with the association between OGM and depression, there is evidence that having higher memory specificity is associated with increased well-being in older adults (Latorre et al., 2013; Ricarte et al., 2011) and may therefore be protective against depression.

As well as contributing to OGM, depression appears to slow down older adults' memory search (Latorre et al., 2013; Serrano et al., 2007), which could be a result of reduced working memory capacity. The evidence from Birch and Davidson (2007) further supports the importance of working memory in relation to OGM suggested by the CaR-FA-X model, and indicates that this has an effect on OGM that is independent of depression or age. However, increased OGM was found to occur in older adults with depression in the absence of significant working memory impairment (Birch & Davidson, 2007), suggesting that OGM in this client group cannot be solely attributed to mood-related impairments in executive functioning. OGM has been found to be most pronounced in response to negative memory cues, (Ricarte et al., 2011; Serrano et al., 2007). In line with the CaR-FA-X model (Williams, 2006; Williams et al., 2007), it is possible that older adults with depression ruminate on negative self-referent information, disrupting specific memory retrieval, or that there is avoidance of specific negative memories as an emotional regulation strategy. However, as none of the studies reviewed have formally assessed rumination or emotional regulation, the role that these factors might play remains speculative.

In contrast to findings in working age adults that suggest OGM is a stable ‘trait’ marker for depression (e.g. Brittlebank et al., 1993), OGM does not appear to remain stable on remission from depression, to respond to negative mood states, or predict depressive relapse in older adults (Haringsma et al., 2010). However, these factors have been investigated by only one study, which had notable limitations in terms of sample recruitment. By comparison, Fromholt et al. (1995) found that recalling low levels of memory detail remained stable on remission from depression. Further longitudinal research in clinical samples would be needed to further investigate the stability of OGM over time in older adults with depression.

In terms of older adult memory phenomena, there is evidence that older adults with depression lose the ‘reminiscence bump’ of enhanced recall for adolescent events (Gidron & Alon, 2007), and that the ‘positivity bias’ usually observed in memory retrieval is diminished (Latorre et al., 2013; Serrano et al., 2007). Older adults with depression may instead demonstrate a bias towards recalling more recent, negative events (Fromholt et al., 1995). Whether these apparent differences are a cause of, or a consequence of, depression in older adults cannot be determined from the existing findings and would require further longitudinal research.

#### *4.3. Clinical Implications*

Studies of Life Review interventions support the use of this approach as a way to improve memory specificity, depression symptoms and wellbeing in older adults. However, the only adequately controlled trial in a clinical sample (Serrano Selva et al., 2012) did not find any significant benefit of Life Review over supportive therapy in terms of depression outcome. Additionally, the finding that autobiographical memory improves on remission of depression through antidepressant treatment (Gallassi et al., 2006) suggests that OGM may improve as a consequence of reduced depressive symptoms, rather than improvements in OGM leading to reductions in depression. Intervening by targeting OGM in older adults therefore does not appear necessary to reduce depression. However, the limited evidence to date suggests that increasing memory specificity may be one mechanism through which depression can be improved in this client group. This is in line with findings in the general adult literature that interventions targeting memory specificity, such as MEST, can improve both memory specificity and depression symptoms (Dalgleish & Werner-Seidler, 2014).

#### *4.4. Limitations*

The inclusion criteria for this review were kept broad due to the relatively low numbers of available articles. As a result, there was great heterogeneity in the studies reviewed in terms of the methodology, quality and samples. Although the literature searches were conducted using a systematic procedure, the current review does not claim to be exhaustive and due to resources available it did not include a search of the grey literature. The definition of the ‘older adult’ population as 50 years and over is a particular limitation. It was initially intended to define the population as 65 years and over, in line with the commonly accepted criteria for older adult mental health services. However from an initial screen of the search results, it was clear that this would leave few articles and exclude many of theoretical interest.

#### *4.5. Recommendations for Future Research*

This review has highlighted some limitations and gaps in the existing literature on OGM in older adults, which suggest directions for future research.

In terms of methodological issues, researchers looking at OGM in older adults need to adopt standardised procedures for administering the AMT to allow comparison between studies. This would also facilitate future systematic and meta-analytic review. When isolating the relationship between depression and OGM, it is also important to ensure that other problems that might influence OGM (e.g. cognitive impairment, PTSD and antidepressant medications) are adequately screened and controlled for.

It was notable that few of the reviewed papers (Ford et al., 2014; Ricarte et al., 2011; Ros et al., 2010) cited the CaR-FA-X model, despite the dominance of this theoretical framework in the wider OGM literature. Research is needed to look more explicitly at different factors of the CaR-FA-X model, especially rumination and functional avoidance, to establish the contributions these make to OGM in this client group. There is a substantial line of research into rumination and repetitive thinking (see Watkins, 2008), and this is leading to the development of interventions for depression such as Rumination-focused Cognitive Behavioural Therapy (RF-CBT; Watkins et al., 2011) and Competitive Memory Training (COMET), which has shown positive outcomes in older adults (Ekkers, 2011). Establishing the relationship between rumination and OGM in older adults would enable more joined-up thinking around clinical approaches. Further longitudinal research would also be beneficial in order to establish whether

OGM is a stable ‘trait’ marker of depression in older adults, and whether OGM can predict depressive relapse in this group.

Finally, there is a need for further clinical trials to help draw firmer conclusions regarding the efficacy and mechanisms of action of Life Review interventions. Ideally, trials are needed on a larger scale and with more in-depth analysis of mediating factors. In progressing this research, it would also seem beneficial to draw on the literature on memory specificity interventions being developed in the wider research, such as MEST. Although the two lines of research appear to have evolved separately, they have converged on similar conclusions around the potential benefits of increasing memory specificity as an intervention for depression.

#### *4.6. Summary and Conclusion*

This evaluative review provides a synthesis of what is currently known about OGM and depression in older adults, using the CaR-FA-X model (Williams, 2006; Williams et al., 2007) as a theoretical framework.

Clear evidence was found that OGM occurs in older adults in the absence of depression, due partly to changes in executive functioning associated with healthy aging. There is also suggestion that OGM in healthy older adults reflects a tendency to integrate memories in terms of self-relevance and a bias against retrieval of specific negative memories. In this respect, OGM in older adults could be considered beneficial to wellbeing in some circumstances, rather than a marker of emotional distress. However, in line with the literature in younger adults, there was strong evidence that the presence of depression in older adults increases OGM. This appears due in part to the effects of depressed mood on executive functioning, as well as possible changes in the relationship individuals with depression have to negative memories. However, the role of rumination and functional avoidance mechanisms in OGM in older adults has not been adequately investigated. It is also unclear to what extent OGM acts as a marker for recurrent depression in older adults and further research is needed.

In terms of clinical implications, there is some support for the use of Life Review interventions for increasing memory specificity and improving depression symptoms. It would be logical for future research in this area to draw on developments in interventions in the working age adult literature and rumination literature. There appears

still to be some way to go in developing our understanding of OGM in the older adult population, and it is hoped that this review will provide direction for the next steps.



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**University of Bath  
Doctorate in Clinical Psychology**

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**Service Improvement Project**

**An evaluation of psychological service  
provision in a palliative care setting**

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**Internal Supervisors:** Dr Claire Lomax and Dr Cathy Dysch

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**Intended Journal:** *Palliative Medicine. This peer-reviewed Journal accepts original articles relevant to multi-disciplinary clinical practice and policy in palliative care.*

## Background

Palliative care is an approach to the treatment of terminal and life-limiting illnesses, which emphasises quality of life and the relief of suffering (World Health Organisation, 2002). Hospices in the UK currently provide palliative care to around 120,000 patients each year (Hospice UK, 2015). Approximately 4% of all deaths annually occur in a hospice setting; patients most likely to receive end-of-life care from a hospice are those aged between 45-64, and those with a cancer diagnosis (Department of Health, 2008).

The distress and suffering experienced by patients who are approaching the end of life is multidimensional. Alongside pain and other physical symptoms, suffering may be related to psychological factors such as depression or anxiety, spiritual and existential factors such as a loss of identity and meaning, and social factors such as the impact of illness on the family (Krikorian, Limonero, & Mate, 2012). Estimates of the prevalence of psychological distress in palliative care settings vary widely (Walker et al., 2013); however one meta-analysis suggests a prevalence of 16.5% for depression, 15.4% for adjustment disorders, and 9.8% for anxiety disorders (Mitchell et al., 2011). The presence of co-morbid depression has a substantial negative impact on health outcomes in various chronic illnesses (Moussavi et al., 2007), and psychological distress has been found to mediate the relationship between physical symptom severity and subjective suffering in advanced cancer (Krikorian, Limonero, Roman, Vargas, & Palacio, 2013). In order to provide effective palliative care and relieve suffering, it is therefore essential to address more than a patient's physical health needs.

There has been increasing attention paid to the provision of psychological support in cancer and palliative care services in national guidelines over the past decade. The NICE guidance on Improving Supportive and Palliative Care for Adults with Cancer (2004) made the following recommendations:

- Psychological wellbeing of patients and carers should be explicitly assessed at key points in treatment.
- All staff involved in direct patient care should provide basic emotional support, including good communication skills.
- Any patients or carers identified as experiencing high psychological distress should be able to access specialist intervention.

- All staff providing psychological support should be adequately trained and supervised.

The NICE guidance recommends developing services that provide a 4-Level model of psychological support. The forms of assessment and intervention provided at each level, and the staff groups involved in delivery, are outlined in **Table 6**.

**Table 6:** *Four Level model of psychological support in cancer services (NICE, 2004)*

Level	Group	Assessment	Intervention
<b>1</b>	All health and social care professionals	Recognition of psychological needs	Effective information giving, compassionate communication and general psychological support
<b>2</b>	Health and social care professionals with additional expertise	Screening for psychological distress	Psychological techniques such as problem solving
<b>3</b>	Trained and accredited professionals	Assessed for psychological distress and diagnosis of some psychopathology	Counselling and specific psychological interventions such as anxiety management and solution-focused therapy, delivered according to an explicit theoretical framework
<b>4</b>	Mental health specialists	Diagnosis of psychopathology*	Specialist psychological and psychiatric interventions such as psychotherapy, including cognitive behavioural therapy

The National Cancer Action Team's (NCAT's) Psychological Support Measures (2010) built on the NICE guidance, recommending specific measures for implementing best practice in the planning and evaluation of services. The recommendations include that



staff providing Level 2 support should attend a National Advanced Communication Skills Training (ACST) course, as well as a regionally developed course in Level 2 psychological skills. The Level 2 course may include training in psychological screening, assessment, and interventions based on Cognitive Behavioural Therapy (CBT) and other therapeutic approaches. The measures also advise that staff working at Level 2 receive regular supervision from a Level 3 or 4 practitioner; these practitioners therefore have a central role in providing training and supervision to other staff, as well as delivering specialist interventions through direct clinical work. \*NCAT (2010) moved away from Level 4 being concerned with ‘diagnosis of psychopathology’, defining Level 4 as a degree of psychological screening, intervention and support that requires the skill-set of a clinical or counselling psychologist or consultant psychiatrist.

The ACST programme has been demonstrated to significantly improve staff confidence in communicating sensitive information in palliative care settings (Wilkinson, Perry, Blanchard, & Linsell, 2008). There is also evidence that CBT-based interventions delivered by non-psychologist professionals who have received brief training, are an effective intervention for anxiety and depression in palliative care (Anderson, Watson, & Davidson, 2008; Moorey et al., 2009). Mannix et al. (2006) found that, following brief CBT training, ongoing supervision was essential for staff to maintain their skills and confidence. These findings suggest that effective psychological support can be provided by palliative care professionals from non-psychology disciplines, when appropriate training and support are in place. The findings also have important implications for the role of Clinical Psychologists as Level 4 practitioners; to use their specialist knowledge to provide appropriate training and supervision to other staff.

### *Current Project*

The purpose of the current project was to examine the psychological services being provided at a hospice in the South West of England. The hospice is a third sector organisation providing end-of-life care to people with cancer and other serious health conditions, and has an annual caseload of approximately 2000 patients. Since 2009, the hospice has employed a Clinical Psychologist for one day per week (0.2wte) to provide direct clinical work to patients and carers, as well as training, supervision and consultation.

The aims of the current project were:

1. To examine the psychological support being provided by staff at the hospice, in relation to NICE and NCAT recommendations.
2. To evaluate the Clinical Psychology service at the hospice, from the perspective of other staff.
3. To explore how other staff groups view the role of the Clinical Psychologist.
4. To provide recommendations to the hospice to inform the future development of psychological service provision.

Specific questions that the project aimed to address were:

1. How does the psychological support provided at the hospice map onto national recommendations from NICE and NCAT?
2. How confident do staff members feel at providing psychological support, and does training attendance increase confidence?
3. What barriers could be addressed to improve the psychological support provided at the hospice?
4. How satisfied are other staff groups with the current Clinical Psychology service?
5. How do other staff groups view the role of the Clinical Psychologist in palliative care?

## **Methods**

A range of methods were selected in order to address the project questions. To examine how the psychological support provided at the Hospice maps onto national recommendations (Question 1), data was collected from Clinical Psychology service records about the activity being conducted at Level 4, including provision of training and support to other staff. A staff survey was also designed, with two sections. *Section A* was designed to gather information from staff concerning service provision at Levels 1, 2 and 3. This included asking about the psychological support being provided by staff members and the training and supervision they had received in relation to national recommendations (Question 1), as well as their confidence (Question 2), and perceived barriers (Question 3). *Section B* was designed to seek feedback on different aspects of

the service provided by the Clinical Psychologist (Question 4), and the staff member's perception of the Clinical Psychologist's role (Question 5). The survey method was chosen in order to try and gain views from as many staff as possible. Advantages of this method were that staff members could complete the questionnaires in their own time and could be assured confidentiality, which it was felt would encourage open responses (Barker, Pistrang, & Elliot, 2002).

Following analysis of the survey data, it was then planned to conduct focus groups to further explore staff perceptions of the Clinical Psychologist's role (Question 5), as well as to generate ideas for recommendations that might help to improve psychological service provision at the Hospice. A semi-structured qualitative interviewing format was selected in order to gain an in-depth account of the issues being explored, and the group format was selected to encourage participants to respond to each other's' ideas and generate a deeper exploration (Barker et al., 2002). However, if staff members were unable to attend a focus group for practical reasons, an individual semi-structured interview was arranged.

## ***1. Clinical Psychology Service data***

Data was collected from Clinical Psychology records concerning activity during the 2013/14 financial year. This included direct clinical work provided to patients and carers, and indirect services provided to staff.

## ***2. Staff Survey***

**2.1. Participants:** All hospice staff with clinical responsibility (approximately 82 permanent and 57 bank staff) were invited to complete a survey about psychological service provision at the hospice. Twenty-eight responses were received, a response rate of 20% of all permanent and bank staff. The teams and professions of the respondents, compared with total permanent staff numbers as at April 2014, are presented in **Table 7**.

**Table 7:** Professional backgrounds and team affiliations of survey respondents, compared with total staff numbers

		Respondents	Total Permanent Staff
<b>Team</b>	Inpatient Unit	12	42
	Clinical Nurse Specialists	5	18
	Family Support Team	5	6
	Therapy Service	4	6
	Day Hospice	3	4
	‘Hospice at Home’ team	1	6
	<b>Total</b>	<b>30<sup>1</sup></b>	<b>82</b>
<b>Profession</b>	Registered Nurse	10	34
	Clinical Nurse Specialist	5	18
	Medic <sup>2</sup>	4	2
	Occupational Therapist	3	4
	Social Worker	3	3
	Physiotherapist	1	2
	Dietician	1	0
	Health Care / Nursing / Social Work Assistants	1	19
	<b>Total</b>	<b>28</b>	<b>82</b>

<sup>1</sup> Two respondents indicated working across two different teams.

<sup>2</sup> The surveyed medics included Trainee General Practitioners who were not permanent staff

**2.2. Materials:** The survey was developed by the lead researcher and the Clinical Psychologist, in consultation with five randomly selected staff members from different professions. The survey included tick-box options and Likert-scale responses providing quantitative data, as well as free-text questions providing qualitative data. Items for *Section A* of the survey were informed by referring to the NICE (2004) and NCAT (2010) guidelines around the training, support and competencies expected for staff working at different levels. Items for *Section B* of the survey were informed by previous service evaluations, for example looking at referrals to clinical psychology in Hospice settings (Alexander, 2004) and at other professionals’ perceptions of clinical psychology services in health

settings (Abrahams & Udwin, 2002; Olson et al., 1988). See **Appendix B** for a copy of the survey.

**2.3. Procedure:** Survey responses were collected between September and December 2013. Staff members were informed of the survey through internal communications and meetings arranged with team leaders. Respondents were assured that their responses would be confidential.

**2.4. Analysis:** For analysis of the quantitative data, non-parametric statistics were used throughout due to the data being at the ordinal level. An inductive thematic analysis was used to analyse the qualitative responses (Braun & Clarke, 2006); this was performed on the data set as a whole, as responses did not always relate exclusively to the question asked. The data were coded and the codes grouped into provisional themes by the lead researcher using NVivo software (QSR International, 2012), then refined into the final themes and sub-themes.

### **3. *Focus Group and Interviews***

**3.1. Participants:** Fifteen survey respondents indicated that they would be interested in a follow-up interview, and were contacted during May 2014. Seven agreed to participate. One focus group (n=5) was conducted with members of the Family Support Team and Therapy Service. Individual interviews were conducted with a Clinical Nurse Specialist and an Inpatient nurse, who were unable to attend the focus group.

**3.2. Materials:** Following preliminary analysis of the survey data, a schedule of open-ended questions was developed to elaborate on themes that had emerged (see **Figure 1**). These questions were used to initiate and structure the focus group/interview discussions.

**3.3. Procedure:** The focus group and interviews were conducted in a semi-structured format by the lead researcher, and were video recorded with consent for transcription purposes. Transcription was completed by the lead researcher

and transcripts were anonymised by removing potentially identifying information.

- *If there was more Clinical Psychology time available at the Hospice, how could this best be used?*
- *What do you think are the responsibilities of the Clinical Psychologist in providing psychological support to patient and carers, and what do you think are the responsibilities of other staff?*
- *What could be done to help to build staff skills and confidence in providing psychological support?*
- *What do you see as the value of having supervision from a Clinical Psychologist?*

*Figure 1: Questions used to structure focus group and interviews*

**3.4. Analysis:** Inductive thematic analysis was conducted on the combined data from the focus group and two individual interviews (Braun & Clarke, 2006). Transcripts were coded and the codes grouped into provisional themes by the lead researcher using NVivo (QSR International, 2012). A second researcher independently reviewed the transcripts and identified provisional themes, which were then discussed and refined. The data was then reviewed again by the lead researcher in relation to the agreed themes, and grouped into the final themes and sub-themes. Throughout the analysis process, the lead researcher recognised her position as a Clinical Psychologist in training who was supervised by the Clinical Psychologist at the hospice, and who therefore might have a bias towards interpreting the data in a way that would positively represent psychology.

## **Findings**

### *Clinical Psychology Service data*

The direct and indirect activity carried out by the Clinical Psychology service during the 2013/14 financial year is summarised below.

#### *Direct Activity*

- 64 referrals received
- 46 new patients seen
- 115 filled clinical appointments

#### *Indirect Activity*

- 31 consultations
- 46 supervision slots
- 30 teaching hours

### ***Survey***

The survey data are presented below under the relevant research questions. Seven overarching themes were identified through the qualitative analysis; these are presented in summary under the relevant research question.

#### ***1. How does the psychological support provided at the hospice map onto national recommendations from NICE and NCAT?***

##### **1.1. Provision of psychological support at the 4 NICE Levels**

All respondents saw providing psychological support as part of their role. Of 27 responses, 12 (44%) identified working at Level 1, and 15 (56%) identified working at Level 2. No respondents felt they were working at Level 3, however 7 (26%) felt they could potentially work at Level 3.

##### **1.2. Attendance at NCAT recommended training courses**

According to hospice records, 8 nurses had attended ACST and 16 staff members had attended Level 2 Psychology Skills training at the time of the survey. Attendance rates for survey respondents are shown in **Table 8**.

***Table 8: Attendance at recommended training courses***

	<b>N</b>	<b>ACST</b>	<b>Level 2 Psychology Skills</b>	<b>Both</b>
All Respondents	27	6 (22%)	6 (22%)	3 (11%)
Level 2 Respondents	15	5 (33%)	5 (33%)	3 (20%)

Reasons given for non-attendance were: not being offered the opportunity (n=8), lack of course availability (n=3), being unaware of the courses (n=3), having equivalent training (n=3), and being new in post (n=3). Eight respondents identified working at Level 2 but had attended neither course; these included professionals who may have had equivalent training.

### **1.3. Attendance at supervision with a Level 3 or 4 Practitioner**

Four of the 6 staff who had attended ACST (67%), and 5 of the 6 staff who had attended Level 2 Psychology Skills (83%), were accessing regular group supervision from the Clinical Psychologist. Of the staff who identified working at Level 2, 10 (67%) attended group supervision.

## **2. *How confident do staff members feel at providing psychological support, and does training attendance increase confidence?***

### **2.1. Confidence Levels**

Respondents rated their level of confidence with six aspect of providing psychological support. Items were rated from 1 to 5, a higher score indicating greater confidence. **Table 9** summarises these responses.

**Table 9:** *Median staff confidence levels in providing psychological support*

<b>Aspect of Psychological Support</b>	<b>N</b>	<b>Median</b>	<b>Range</b>
Recognising distress	28	4	3 to 5
Providing supportive listening	28	4	3 to 5
Communicating sensitive information	28	5	3 to 5
Assessing/screening for psychological distress	28	4	1 to 5
Using psychological techniques (e.g. problem-solving)	28	4	1 to 5
Recognising when onward referral is needed	28	4	1 to 5

Generally high levels of confidence were reported. Some staff gave low ratings for assessing distress and using psychological techniques; however, not all staff used these skills in their role. Significant positive correlations were found between the



frequency with which respondents performed assessments and their confidence in doing so (Spearman's  $r=0.406$ ,  $p<.05$ ), and the frequency with which they used psychological techniques and their confidence in doing so (Spearman's  $r=0.477$ ,  $p<.05$ ). Those who used these skills regularly reported greater confidence.

## **2.2. Confidence and Training Attendance**

Using independent-samples Mann-Whitney U tests, confidence ratings for each of the six aspects of psychological support were compared between those who had attended recommended training courses and those who had not. No significant differences were found between those who had attended ACST ( $n=6$ ) and those who had not ( $n=21$ ), or between those who had attended Level 2 Psychology Skills ( $n=6$ ) and those who had not ( $n=21$ ; all  $p$  values  $>.05$ ). As these courses primarily target nurses, the analyses were repeated using data from nurses only. No significant differences were found between nurses who had attended ACST ( $n=5$ ) and those who had not ( $n=9$ ), or between nurses who had attended Level 2 Psychology Skills ( $n=3$ ) and those who had not ( $n=11$ ; all  $p$  values  $>.05$ ). It is important to note the very small sample sizes used in these analyses, which limits the conclusions that can be drawn.

## **3. *What barriers could be addressed to improve the psychological support provided at the hospice?***

### **3.1. Qualitative Theme 1: Barriers to providing Psychological Support**

Within this theme, five sub-themes were identified: *Knowledge and Confidence* (26 references), *Space* (15 references), *Environment* (11 references), *Time* (10 references) and *Resources* (9 references).

A lack of knowledge and confidence was the most frequently expressed barrier and many staff reported a desire for further training. Staff identified a lack of knowledge as to how to identify and screen for psychological distress, and a lack of confidence in their ability to provide support:

*"I feel that my patients would benefit if I was able to establish psychological distress, as sometimes I care for people who are obviously in some difficulties but I do not know how to proceed."* (Respondent 5)

Some respondents indicated that they had knowledge and skills that were being underutilised in their role:

*“...there are a few staff...including myself who have qualifications in counselling. I would like my skills to be utilised better and to be given the opportunity to use them more.”* (Respondent 24)

Practical barriers were described, including a shortage of private spaces, distractions and interruptions, time constraints, and the pressures of meeting patients’ medical needs:

*“There are times when no quiet room is available to use to have these conversations.”* (Respondent 27)

*“I feel IPU staff could help patients with psychological needs if there was more time (uninterrupted) to do this.”* (Respondent 3)

Finally, there were references to the need for more written resources relating to psychological support:

*“Literature would be a great idea for practitioners to give to patients/carers and to use with patients.”* (Respondent 14)

#### **4. How satisfied are other staff groups with the current Clinical Psychology service?**

Respondents rated their satisfaction with various aspects of the Clinical Psychology service. Ratings were given only by respondents who had made use of each service. Median ratings were predominantly 4 (‘satisfied’) or 5 (‘very satisfied’). **Table 10** summarises these findings, and further data relating to referrals, consultation, supervision and training are presented below.

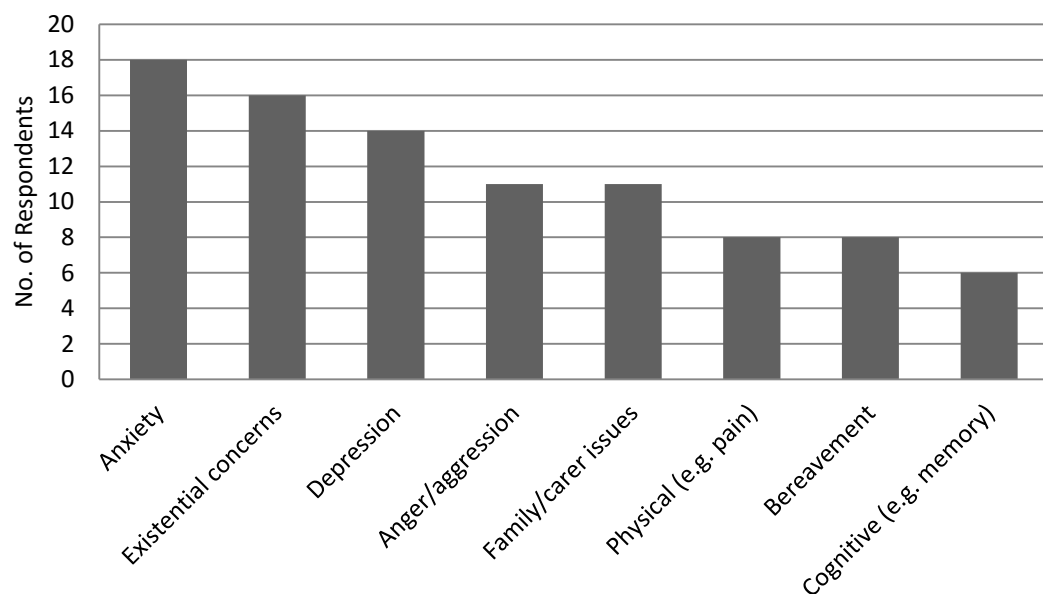
**Table 10:** Staff satisfaction with services provided by the Clinical Psychologist

<b>Clinical Psychology Service</b>	<b>N</b>	<b>Median</b>	<b>Range</b>
Referral Process	20	4	2 to 5
Written feedback on referrals	20	4	2 to 5
Verbal feedback on referrals	20	4	2 to 5
Consultation	18	5	2 to 5
Supervision	12	5	4 to 5

In-service training quality	11	4	2 to 5
In-service training availability	22	3	2 to 5

#### 4.1. Referrals

Respondents were asked to indicate the reasons for which they had referred to Clinical Psychology; responses are shown in **Figure 2**. Respondents were also asked whether they referred all patients or carers who they thought might require Level 3 or 4 input: 13 (65%) said yes and 7 (35%) said no. Reasons for not referring were identified in the thematic analysis (see 4.1.1.).



**Figure 2:** Reasons for referral to Clinical Psychology

##### 4.1.1. Qualitative Theme 2: Access to Clinical Psychology

This theme comprised of four subthemes: *Waiting Times* (16 references), *Process Issues* (8 references), *Patient Choice* (6 references) and *Access for Outpatients* (5 references).

Respondents highlighted that the Clinical Psychology service had limited availability and this could result in long waiting times. This was given as a reason for not referring, particularly when patients are very unwell:

*“Sometimes they are too poorly by the time [the Clinical Psychologist is available].”* (Respondent 26)

Comments made in relation to the Clinical Psychology referral process included that completing the referral form was time consuming, that there was a lack of clarity around appropriate referrals, and that feedback was not always received.

It was felt that Clinical Psychology was less accessible for outpatients due to the need to travel. Again, this was given as a reason for not referring patients who might benefit:

*“Needing to come to [the Hospice] rather than home visit.”* (Respondent 9)

Some respondents noted that they might not refer due to patient choice:

*“[I] discuss with patients first so may not refer all. Depends on what they want.”* (Respondent 24)

## **4.2. Consultation**

Of 18 respondents, 1 indicated that they sought consultation from the Clinical Psychologist weekly, 3 ‘twice per month’, 6 ‘once per month’, and 8 ‘less than once per month’.

## **4.3. Supervision**

Twelve respondents (43%) indicated that they attended a supervision group with the Clinical Psychologist on a monthly or six-weekly basis.

### *4.3.1. Qualitative Theme 3: Supervision with the Clinical Psychologist*

This theme comprised of two subthemes: *Barriers to Supervision* (11 references) and *Positive Feedback* (4 references).

In line with the quantitative feedback, positive comments were made regarding the quality of supervision with the Clinical Psychologist:

*“I feel [supervision] works very well.”* (Respondent 2)

However, respondents raised some barriers to attending, such as a lack of other staff available to provide cover:

*“Not released from work, no cover, phone not covered.”* (Respondent 9)

#### **4.4. Training**

Twelve respondents (43%) had attended at least one in-service training event provided by the Clinical Psychology service.

##### *4.4.1. Qualitative Theme 4: In-Service Training*

This theme comprised two subthemes: *Requests for Training* (16 references) and *Barriers to Training* (13 references).

A desire was clearly expressed for more psychological training generally, including repeating past sessions for new staff:

*“None of the [training topics] since I started working here have been available. More of it. More often.”* (Respondent 26)

Barriers to attending training were seen as a lack of availability, a lack of awareness, and that training sessions are not always accessible to all (e.g. part-time or bank staff):

*“I don’t work on the day the psychologist is in, which is why I have poor attendance.”* (Respondent 16)

### **5. *How do other staff groups view the role of the Clinical Psychologist in a Palliative Care setting?***

#### **5.1. Role Importance and Service Provision**

Respondents rated how important they viewed four aspects of the Clinical Psychologist’s role to be, from 1 (‘not at all’) to 5 (‘extremely’). For each area, they also rated the current amount of service provision as to whether it was ‘not enough’, ‘about right’ or ‘too much’. Responses are summarised in **Table 11**.

**Table 11:** Ratings of the importance and amount of Clinical Psychology service provision

Aspect	Importance			Provision			
	N	Median	Range	N	Rating Frequencies		
					Not enough	About right	Too much
Direct clinical work	26	5	4 to 5	27	21 (78%)	6 (22%)	0 (0%)
Consultation	26	5	3 to 5	26	15 (58%)	11 (42%)	0 (0%)
Supervision	24	4	3 to 5	22	12 (55%)	10 (45%)	0 (0%)
Training	26	4	3 to 5	27	16 (59%)	11 (41%)	0 (0%)

#### 5.1.1. Qualitative Theme 5: Relationships with the Clinical Psychologist

This theme comprised of two sub-themes: *Positive Relationships* (14 references) and *Lack of Presence* (11 references).

Some staff commented that the Clinical Psychologist is well integrated into the Hospice. Positive feedback was also given about how approachable the Clinical Psychologist is when present:

*“[The Clinical Psychologist] is always approachable, however busy she is”* (Respondent 11)

Contrastingly, some respondents commented that they do not feel the Clinical Psychologist is approachable or integrated into the Hospice, due to a lack of presence.

*“As I do not know the psychologist and rarely see her I would find it difficult to approach this service”* (Respondent 5)

#### 5.1.2. Qualitative Theme 6: Clinical Psychology Hours

The need for additional Clinical Psychology hours was a strong theme. This could be divided into three sub-themes: *General Availability/Ambiguous* (28 references), *Direct Work* (22 references), and *Staff Support* (6 references).

Some respondents were not specific about what extra Clinical Psychology time would be useful for:

*“The availability of a psychologist only 1 day a week feels inadequate”*

(Respondent 2)

However, in line with the quantitative findings, many felt more hours were needed for direct clinical work:

*“I feel we need more than one clinical psychologist working one day a week- so many patients would value input but cannot access service”*

(Respondent 9)

Some specifically highlighted a need for additional hours to increase staff support:

*“More hours to offer...more education/support to staff”* (Respondent 11)

#### 5.1.3. Qualitative Theme 7: The Value of Clinical Psychology

This final theme consisted of three sub-themes: *Presence in MDT* (14 references), *Value to Staff* (5 references), and *Value to Patients* (5 references).

Having a Clinical Psychologist as a presence in the multi-disciplinary team (MDT) was seen as valuable, bringing a different perspective to clinical discussions:

*“[Clinical Psychology] brings useful psychological focus to MDT meetings that can otherwise be very medical”* (Respondent 17)

The value of Clinical Psychology in providing direct clinical work was highlighted by several respondents, while some commented on the value in relation to improving staff skills and confidence:

*“It has been great to experience having a clinical psychologist in the team and also those in training. It has increased my awareness and knowledge and confidence re providing psychological support, something I am passionate about”* (Respondent 15)

## ***Focus Group and Interviews***

Five superordinate themes were identified through the thematic analysis on the combined data from the focus group and interviews: 1) ‘Staff Skills and Confidence’, 2) ‘Collective Responsibility’, 3) ‘Multiple Perspectives’, 4) ‘Clinical Psychology Role’, and 5) ‘Clinical Psychology Presence and Hours’. Each theme is described below with examples.

### **1. Staff Skills and Confidence**

The skills needed to provide psychological support and staff confidence in applying these skills was a strong theme. Within this, three subthemes were identified: *Low Confidence* (23 references), *Training and Supervision* (23 references), and *Uniqueness of Palliative Care* (11 references). All subthemes were identified across the focus group and both interviews.

**1.1.Low Confidence:** It was suggested that low confidence in responding to distress can trigger inappropriate referrals to Clinical Psychology and means that staff may not take opportunities to provide support on the inpatient unit:

*“I kind of think sometimes people refer because someone’s really upset, it’s kind of in their face at the time and they...don’t know how to manage that.”* (Focus Group Participant 1)

*“...when you’re not so confident, you sort of see [psychological distress] but you don’t want to go there. So it’s so easy to then get distracted and go and do something else...and that opportunity’s missed.”* (Interview 2)

**1.2.Training and Supervision:** Training was seen as important for helping staff to develop skills and confidence. Suggestions included incorporating training into staff inductions and running frequent skills-based sessions. Clinical supervision was also identified as a helpful avenue for developing skills and confidence, although variability in supervision between teams was noted:

*“...in this [Family Support Team] we have quite a lot of opportunities to reflect, discuss and share ideas.... Whereas for the nurses, there doesn’t seem to be that.”* (Focus Group Participant 4)



**1.3.Uniqueness of Palliative Care:** The hospice setting was highlighted as being different to other healthcare environments, in terms of the skills required and the emotional impact of the work:

*“I think that we work in a unique environment, and I think that’s really important to recognise. It’s not a generalist environment. And that does take special skills...”* (Focus Group Participant 5)

*“In my work in the community you’re sort of advising people who are getting better, and [at the Hospice] that’s not necessarily the case. You’re just trying to give them a better quality of life and to be able to sort of achieve their goals in whatever time they have got, really. It’s very different, really. It was a bit of a shock to me.”* (Focus Group Participant 3)

## **2. Collective Responsibility**

This theme included two subthemes, which were identified across the focus group and both interviews: *Everyone has a Role* (19 references), and *Barriers* (11 references).

**2.1. Everyone has a Role:** Providing psychological support was strongly seen as a shared responsibility:

*“...it’s our responsibility, all of us, to be trying to address stuff, not thinking ‘well that’s not ours to do, that’s the psychologist’s role’. Emotional support, psychological support is for us all.”* (Interview 1)

Staff members who have a lot of direct patient contact were seen as having an important role in identifying distress. There was also a suggestion that providing support as part of routine care can be less stigmatising than being referred to a specialist:

*“I feel that the psychology part should be done by the nurses that are on the unit...otherwise it becomes very clinical doesn’t it? You become- you’re ‘going to see the psychologist’- when I think a lot of things could be dealt with on a...day-to-day basis.”* (Interview 2)

**2.2. Barriers:** Time, the pressures of other clinical duties, and staff not prioritising distress screening were all raised as potential barriers to providing psychological support in practice.

### **3. Multiple Perspectives**

This theme comprised three subthemes: *Beyond the Medical Model* (20 references across the focus group and interview 2), *Value of Multidisciplinary Working* (22 references in the focus group only), and *Professional Boundaries* (29 references in focus group only).

**3.1. Beyond the Medical Model:** Participants highlighted the importance of thinking broadly about a patient's psychosocial needs rather than focusing on medical management, and the benefits of using distress screening tools:

*"[It's really good] that people are given a bit of time to [express themselves] as well and it's not just about your medical symptoms. I mean it is as important to be able to...help someone with their psychological distress and the impact on their family as well."* (Focus Group Participant 1)

*"...you really find out what's important to [patients]. And what you think might be important, you suddenly realise is not important at all...this is what's important, like the fact they can't drive their car anymore and stuff like that, which you didn't give a second thought about."* (Interview 2)

**3.2. Value of Multidisciplinary Working:** Several comments were made about the value of being part of a MDT in terms of hearing different perspectives on clinical issues.

*"No one person can understand loads of different layers. But what we bring as a collective is all those layers, you see, or a significant amount of them, which can help."* (Focus Group Participant 1)

**3.3. Professional Boundaries:** It was also considered important to be aware of professional boundaries. A lack of clarity over distinctions between Clinical Psychology and other roles (e.g. Social Work) was mentioned:

*“Our roles are quite sort of subtle. I mean with bereavement support we say “we are not counsellors, we are giving bereavement support”. But quite often there’s very complex clients, and...there could easily be more people who could have input from [the Clinical Psychologist] ...” (Focus Group Participant 2)*

#### **4. Clinical Psychology Role**

Three subthemes related to staff’s understanding of the Clinical Psychologist’s role: *Indirect Work* (47 references across the focus group and both interviews), *Role Information* (22 reference in the focus group only) and *Direct Clinical Work* (4 references across interviews 1 and 2).

**4.1. Indirect Work:** Providing training, supervision and consultation was seen as an important way for the Clinical Psychologist to support staff with their clinical work, and with the emotional impact of their work:

*“I don’t think it’s put all of the eggs in just direct care. It’s about training, it’s both. I definitely see it’s about a balance there.” (Focus Group Participant 5)*

*“...I see [Clinical Psychology] supporting staff to get them more confident; more training, more role-play, that sort of thing.” (Interview 2)*

Supervision from the Clinical Psychologist was also identified as an avenue for supporting staff with the emotional impact of their work:

*“...You can talk through your own issues with patients too...as a debrief, after people have died, or you know, after an event, to be able to make sense of feelings yourself.” (Interview 1)*

**4.2. Role Information:** Comments were made regarding a lack of knowledge about the role of the Clinical Psychologist, and when it is appropriate to make a referral:

*“I do think sometimes the reason why referrals are so vague- one of the issues will be around people just not knowing. So a lot of people’s referring will be*

*based on...their experience of what they think a Clinical Psychologist does, rather than maybe based in reality.” (Focus Group Participant 1)*

Related to this, it was suggested that written information on the Clinical Psychology service would be helpful for both staff and patients.

**4.3. Direct Clinical Work:** There was recognition that the Clinical Psychologist has a responsibility for working directly with clients or situations that are more complex than other staff might work with:

*“[The Clinical Psychologist’s responsibility is] the level of need that is above and beyond what the medical staff and the nursing staff feel that they can provide, and the family support team feel that they can provide, for the patients and the families.” (Interview 1)*

## **5. Clinical Psychology Presence and Hours**

This final theme comprised two sub-themes: *Lack of Clinical Hours* (22 references across the focus group and interview 1) and *Lack of Team Presence* (14 references in the focus group only).

**5.1. Lack of Clinical Hours:** The limited hours for direct clinical work were raised as a concern, particularly due to long waiting times for patients who have deteriorating health:

*“I think with regard to referring patients to psychology, it’s the waiting time really. Because it can be a significant number of weeks, and that’s a long time for somebody with a limited prognosis.” (Interview 1)*

The lack of clinical hours was also suggested to impact on whether or not referrals are made to the Clinical Psychology service, highlighting that there could be unmet needs which are not recorded:

*“I think there’s a risk when there isn’t a lot of time for people to discount something without even thinking about it. So we don’t know about those we*

*haven't referred. So there's that chunk who are "oh well, they're going to die before [the Clinical Psychologist]'s around again", therefore did that need get met, ever?"* (Focus Group Participant 5)

**5.2. Lack of Team Presence:** Having Clinical Psychology available one day per week was described as having various levels of impact on the team, for example limiting access to consultation and training. One concern was that the lack of presence can mean psychological perspectives are not always considered:

*"I think if you're present in the building more often, it gets people thinking. And I think if you're not at the MDT meeting for example...certain perspectives will be forgotten because you haven't got anyone banging that drum."* (Focus Group Participant 1)

## **Discussion**

The findings of the evaluation project are discussed below in relation to the questions the project aimed to address.

### **1. How does the psychological support provided at the hospice map onto national recommendations from NICE and NCAT?**

The staff members who contributed to the project overwhelmingly saw psychological support as an aspect of their role. There was recognition of a collective responsibility, and that staff providing frequent direct care can be well-placed to identify psychological distress. The importance of thinking broadly about the person and not solely their medical care was also a significant theme. It must be noted that the staff members who participated in the evaluation were more likely to be those who saw psychological support as important; however the findings suggest there is an emphasis on psychosocial thinking across the hospice.

In relation to the NICE (2004) Levels of psychological support, all survey respondents felt they were working at Level 1 or 2, although some felt they could work at a higher level given appropriate training and opportunity. Notably, no respondents identified working at Level 3 currently. A lack of Level 3 practitioners can place additional

pressures on Level 4 practitioners to provide this level of support, which may not be the most efficient use of specialist resources (Macmillan Cancer Support, 2011).

In terms of attendance at recommended training programmes for Level 2 staff, the hospice could be said to be taking appropriate steps towards meeting the recommendations of NCAT's (2010) Psychological Support measures, with scope for improvement. There were eight staff members who identified working at Level 2 but who had not attended either ACST or Level 2 Psychological Skills training. Five of these staff were doctors or social workers, who may have received equivalent training as part of their professional qualifications. However, only 20% of the staff working at Level 2 had attended both training courses, with a lack of opportunity and availability being cited as the main reasons. In terms of supervision, two-thirds of those working at Level 2 were attending group supervision with the Clinical Psychologist on a monthly or six-weekly basis. NCAT's (2010) Psychological Support measures suggest that Level 2 practitioners should receive one hour of clinical supervision per month with a Level 3 or 4 practitioner, but does not stipulate whether this is in group or individual format. Given the limited capacity at Level 4, providing supervision in groups is likely to be the only feasible option for the Hospice, however the survey indicates a need for increased availability and frequency in order to meet the recommended standards. Since the distribution of the survey, further Level 2 Psychology Skills courses and additional supervision groups have been provided by the Clinical Psychology service, which will help to improve the hospice's Level 2 provision.

Offering additional training and supervision hours means that the Clinical Psychologist dedicates more time to indirect work, at the cost of direct work. A lack of Level 4 clinical hours emerged as a serious concern through the survey and interviews. Importantly, it was suggested that poor availability means staff might not consider referral to Clinical Psychology as an option; therefore, referral rates are unlikely to reflect the true level of need. NICE (2004) guidance suggests that 10-15% of people with advanced stage illness are likely to require specialist psychological or psychiatric services. The hospice currently supports approximately 2000 patients per year. Given these figures, it could be expected that between 200-300 patients attending the hospice annually might benefit from access to Clinical Psychology; however during 2013/14, 64 referrals were made and only 46 new patients accessed the service. This supports the staff perception that there is a substantial shortfall in the direct clinical provision at Level 4.

## **2. How confident do staff members feel at providing psychological support, and does training attendance increase confidence?**

Staff confidence levels were good for basic skills such as listening and communicating, which NICE (2004) suggests all staff in clinical roles should be able to demonstrate. Confidence in more specialist skills such as assessing distress and delivering psychological interventions was good for staff who identified using these skills in their role. The qualitative data suggested that a lack of confidence can be a barrier to providing psychological support, with training from Clinical Psychology being proposed as one way to improve this.

No significant differences were found in confidence levels between survey respondents who had attended the ACST or Level 2 Psychology Skills training and those who had not. However, very small sample sizes were involved in these analyses; therefore no conclusions can be drawn about the relationship between training attendance and confidence from this evaluation. There is an established evidence base that suggests such training courses do have a positive effect on confidence levels (e.g. Wilkinson et al., 2008).

## **3. What barriers could be addressed to improve the psychological support provided at the Hospice?**

The main barrier identified was a lack of knowledge and confidence, with a clear desire expressed for increased access to training. Additional barriers were mainly practical in nature and linked to the challenges of working in a busy clinical setting, such as access to quiet spaces and having time aside from other core duties. A lack of resources (e.g. information leaflets) regarding psychological support and the Clinical Psychology service was a practical barrier that could be readily addressed.

## **4. How satisfied are other staff groups with the current Clinical Psychology service?**

The feedback from staff on the Clinical Psychology service was extremely positive, particularly for consultations and supervision. However, lower levels of satisfaction were expressed with the availability of training and the accessibility of clinical services. The amount of provision across all aspects of the service was highlighted as feeling insufficient to meet needs.

The rate that survey respondents reported seeking consultations would suggest a much higher frequency per year than the number recorded by the Clinical Psychologist (31). It is possible that staff classify different types of discussion (e.g. brief informal chats) as consultations, whereas the Clinical Psychologist only recorded more formal discussions. The extent of the indirect work delivered by the Clinical Psychologist could potentially be underestimated using documented figures alone.

#### **5. How do other staff groups view the role of the Clinical Psychologist in palliative care?**

Staff appeared to have a broad view of the role of the Clinical Psychologist, recognising that it encompasses direct work at a 'complex' level, indirect work through other staff and staff support. Clear themes emerged from both the survey and interviews regarding the value that having a Clinical Psychologist adds to MDT working; bringing an important psychosocial perspective to clinical discussions that can otherwise be medically focused.

#### **Outcome**

A report on the findings of this project was presented to the Patient Services Director at the hospice in November 2014. The following recommendations were made:

1. To produce written information leaflets and resources about the Clinical Psychology service, to better inform staff and patients/carers.
2. To continue efforts to increase access to training in psychological skills for all clinical staff, and consider the inclusion of psychological skills training as part of clinical staff inductions.
3. To look at ways to increase the provision of Level 3 psychological support, for example, by enabling any staff who have existing qualifications in psychological therapies, and who wish to do so, to have allocated time for this in their roles.
4. To increase the time available to Clinical Psychology, in order that the service can continue to deliver staff training, supervision and support, and enable adequate and timely access to Level 4 interventions for all patients who require this.



During a meeting between the researcher, the Patient Services Director and Clinical Psychologist, provisional action plans were developed to address each of these recommendations:

In the short term (during the remainder of the 2014/15 financial year), the Patient Services Director committed to allocating additional funding (<0.1wte) to Clinical Psychology on a temporary basis, to support the development of service information leaflets and resources for common psychological difficulties. It was also agreed to develop a Level 1 Psychological Skills course that will be mandatory for all clinical and non-clinical staff who have not received training at Level 2 or higher, with the aim of improving skills and confidence. This was planned to be delivered to existing staff as a baseline by the end of 2014/15, then on a quarterly basis as part of the induction programme for new staff.

Longer-term, the Patient Service Director recognised the need to develop service provision at Levels 3 and 4, and expressed commitment to using the report to prospectively plan services. A plan was developed to identify staff with existing qualifications that would allow them to work at Level 3, and to monitor referrals to establish the need at this level. To better meet need at Level 4, it was planned to put forward a proposal to trial an increase in Clinical Psychology hours to between 0.4-0.5wte through a fixed-term Band 7 post, with a timescale of two years to re-evaluate.

The results and outcome of the project were fed back to hospice staff through a lunchtime presentation and discussion. This was attended by around 12 staff members, who gave positive feedback regarding the project and its potential impact.

## **Implications**

Through an evaluation of one palliative care setting, this project has demonstrated some of the challenges of implementing national guidelines in practice. The provision of psychosocial support was clearly seen as very important by staff, suggesting that the palliative care principle of relieving distress in all domains was well embedded into the hospice culture. Although there was scope for improvement, staff confidence in providing psychological support was fair, as was access to the recommended training and supervision for Level 2 staff. Even with these factors in place, staff working at

Levels 1 and 2 may find it difficult to prioritise psychological screening and support due to practical barriers associated with the demands of their role.

Level 4 practitioners have a central role in providing training and supervision under national guidelines; however providing these services when limited time is funded can compromise capacity for direct clinical work. As highlighted by Macmillan (2011), a lack of trained Level 3 practitioners nationally is a problem in being able to deliver the NICE (2004) recommended levels of psychological support, and can place additional pressures on Level 4 practitioners such as Clinical Psychologists.

The findings of this project suggest that Clinical Psychology is viewed by other professionals as a valuable addition to the palliative care team, helping to ensure that patients' and carers' psychological needs are thought about and appropriately addressed. It is essential that Clinical Psychologists in palliative care find ways to monitor and document the impact of their work, in order to demonstrate the value that they bring and encourage continued investment.

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**University of Bath**  
**Doctorate in Clinical Psychology**

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**Main Research Project**

**Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome and Insomnia**

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## **1. Introduction**

### ***1.1. Chronic Fatigue Syndrome***

CFS is estimated to affect between 2 and 4 people per 1000 in the UK (National Institute for Health and Clinical Excellence, 2007). The International Consensus Criteria proposed to define the illness (ICC; Carruthers et al., 2011) outline the primary clinical feature as a marked loss of energy and prolonged recovery period following mental or physical exertion. Sleep disturbance is a common feature of CFS and is said to take two main forms. These are: a) a disrupted sleep pattern, which may include insomnia and frequent night-time awakenings and/or prolonged sleep and daytime napping, and b) unrefreshing sleep, including excessive sleepiness and exhaustion regardless of sleep duration (Carruthers et al., 2011).

### ***1.2. Sleep Disturbance in CFS***

Researchers have investigated sleep disturbance in CFS using polysomnography, actigraphy and electro-encephalogram (EEG) recordings (for reviews, see Jackson & Bruck, 2012; Mariman, Vogelaers, et al., 2013). Although as many as 87-95% of patients with CFS report having poor quality, non-restorative sleep (Mariman, Vogelaers, et al., 2013), there is no consistent evidence that their sleep structure (e.g. sleep onset latency, number of awakenings) is different to that of healthy controls. Several authors have therefore concluded that there is a misperception of sleep quality in CFS (e.g. Majer et al., 2007; Reeves et al., 2006; Watson et al., 2003), which may be driven by psychological factors (Mariman, Vogelaers, et al., 2013).

There are some findings from EEG studies that patients with CFS have impaired sleep homeostasis, the ability to regulate the intensity of sleep by adjusting the amount of slow-wave sleep and delta activity according to need (Armitage et al., 2007; Decker, Tabassum, Lin, & Reeves, 2009), although evidence for this is mixed (Jackson & Bruck, 2012). There is also emerging evidence that patients with CFS have greater levels of physiological arousal during sleep than healthy controls, as indicated by a higher rate of cyclical alternating pattern (CAP; Guilleminault et al., 2006) and reduced heart-rate variability (e.g. Boneva et al., 2007). These findings may suggest a state of hypervigilance during sleep (Jackson & Bruck, 2012).

It has been suggested that the apparent misperception of sleep quality in CFS may be in part due to a misattribution of fatigue symptoms as reflecting poor sleep, as patients

expect that sleep should reduce their fatigue (Westcombe & O'Dowd, 2012). If an individual experiences fatigue on waking, it is understandable for them to perceive they have not slept well (Mariman, Vogelaers, et al., 2013). However, while sleep reduces sleepiness, it does not necessarily reduce fatigue (associated with a lack of muscle strength, low energy levels and neurocognitive complaints), which may have other causes. Although both sleepiness and fatigue are forms of 'tiredness', there is evidence that they are different constructs and do not necessarily correlate closely (Hossain et al., 2005).

In a recent qualitative study of the experience of sleep in CFS, Gotts, Newton, Ellis, and Deary (in press) identified sleep as a significant part of the illness. Themes that emerged from their interviews with CFS patients included that poor sleep is seen as having a significant impact on daytime functioning, quality of life, and the severity of fatigue symptoms. It is therefore clear that, whether or not sleep is objectively disturbed in CFS, the subjective experience of poor sleep can have a significant impact on wellbeing and functioning.

### *1.3. Sleep Disturbance in Insomnia*

Similarly to patients with CFS, the phenomenon of misperceiving sleep quality is a consistent finding in patients reporting insomnia as their primary concern, or co-morbid with other health conditions (for a review, see Harvey & Tang, 2012). People with insomnia commonly report poor quality non-restorative sleep, in the absence of objective markers of sleep disturbance. Like in CFS, patients with primary insomnia have been found to have a tendency to misattribute fatigue to poor sleep (see Harris & Carney, 2012). People with primary insomnia also show an elevated CAP rate as found in patients with CFS (Parrino, Milioli, De Paolis, Grassi, & Terzano, 2009), which these authors suggest may be a physiological marker of cognitive processes (such as anxiety) underlying insomnia.

These findings raise interesting questions regarding the similarities and differences in the sleep disturbances of people with CFS and insomnia. A recent study was the first to directly compare sleep in patients with CFS and primary insomnia (Neu, Mairesse, Verbanck, & Le Bon, in press). This study found that both groups were comparable to healthy controls on objectively recorded sleep variables, except that both patient groups had similarly elevated micro-arousals. They also found support for previous findings of impaired sleep homeostasis in CFS patients. Both groups self-reported poorer sleep

quality and similarly elevated levels of fatigue, depression and anxiety compared to controls (Neu et al., in press). This study indicates comparable levels of misperception about actual sleep in CFS and insomnia. Such findings suggest that both CFS and insomnia might share an underlying aetiology (Mariman, Vogelaers, et al., 2013).

#### *1.4. Cognitive-Behavioural Models*

Cognitive-behavioural models have implicated a number of factors in the vulnerability to and maintenance of both CFS and insomnia. In terms of vulnerability, Surawy, Hackmann, Hawton, and Sharpe (1995) proposed that beliefs about the importance of maintaining high standards and beliefs about the importance of psychological resilience are central to CFS. These characteristics may contribute to a tendency to overestimate the impact of fatigue on performance, and to prefer somatic rather than emotional explanations for symptoms (Surawy et al., 1995). Research has supported the suggestion of elevated levels of perfectionism (e.g. Kempke et al., 2011) and negative beliefs about emotions (see Rimes & Chalder, 2010) in CFS. Vulnerability factors for insomnia are also thought to include perfectionism, with findings of elevated perfectionistic thinking styles, such as high personal standards and concerns about making mistakes (Lundh, Broman, Hetta, & Saboonchi, 1994; Vincent & Walker, 2000), although this relationship may be mediated by emotional distress (Jansson-Frojmark & Linton, 2007).

Common cognitive-behavioural maintenance factors that have emerged from the CFS literature are: an enduring tendency to attribute symptoms to physical causes; negative beliefs about the consequences of activity and fatigue (such as that exercise will lead to worsened symptoms, and that fatigue will negatively affect performance); and an attentional bias to signs of fatigue (for a review, see Knoop, Prins, Moss-Morris, & Bleijenberg, 2010). Factors commonly identified as maintaining insomnia include: having unwanted repetitive thoughts (i.e. worrying or ruminating) while trying to fall asleep; holding unhelpful beliefs about the importance of sleep and consequences of not sleeping; and an attentional bias to signs of tiredness. These factors have been well-supported by insomnia research (see Carney, Harris, Moss, & Edinger, 2010; Espie, Broomfield, MacMahon, Macphee, & Taylor, 2006; Harvey, 2002; Harvey, Tang, & Browning, 2005).



### ***1.5.Aims***

There are clear similarities between the research findings relating to patterns of sleep disturbance in CFS and in insomnia. Both groups commonly report tiredness and subjectively disturbed sleep. The similarities make sense theoretically, given the overlap between the cognitive-behavioural formulations of each disorder in terms of vulnerability factors such as perfectionism, and maintaining factors such as unhelpful beliefs or misattributions about symptoms. This leaves the important question of where the differences might lie. To the best of our knowledge, only one study has directly compared disturbed sleep in CFS and insomnia, and this study has a primary focus on objectively measured sleep characteristics (Neu et al., in press). Cognitive factors relating to sleep and fatigue have not previously been compared in these groups.

The current study aimed to address this gap in the literature by comparing participants with primary insomnia and patients with CFS in terms of their self-reported sleep, fatigue, and psychological characteristics. Of primary interest was to establish whether there are differences in the levels of fatigue, sleepiness and sleep disturbance reported by the two groups. A secondary aim was to look at how the groups differ in terms of cognitions about fatigue and sleep. Finally, key factors considered significant to the cognitive-behavioural models of CFS and insomnia were compared, to look at the extent to which these differentiate the groups.

## **2. Method**

### ***2.1. Overview***

A cross-sectional between groups design was used, comparing 1) patients with a clinical diagnosis of CFS, 2) people with a primary complaint of insomnia, and 3) healthy community controls. It was originally planned to subdivide the CFS sample into two groups according to whether or not they reported a clinical level of insomnia, however due to the size of the final sample this was not feasible. Patients with CFS were recruited through two specialist NHS services in the South West. In the absence of an accessible sleep clinic population, the Insomnia and Healthy Control groups were community samples recruited via social media. The study protocol was approved by the University of Bath Department of Psychology Ethics Committee, the East Midlands

Research Ethics Committee (REC Reference 14/EM/1297), and by the relevant NHS Trust Research & Development departments.

## **2.2. Participants**

Inclusion criteria for all groups were: 1) aged 18 or above, 2) sufficient English language ability to complete the questionnaires, 3) no known diagnosis of a sleep disorder other than insomnia (e.g. narcolepsy, sleep apnoea, restless leg syndrome), and 4) not having received individual CBT for insomnia or fatigue in the past two years. Participants taking medications for sleep, depression, or other conditions were included. **Figure 3** shows a CONSORT flow diagram for all groups. Demographic information is presented in **Table 12**.

Power calculations were performed based on between group differences in fatigue severity on the Chalder Fatigue Scale (ChalderFS; Chalder et al., 1993). Cella and Chalder (2010) found a large effect size (Cohen's  $d= 1.94$ ) between CFS patients and a community sample on the ChalderFS. Using a different fatigue measure, Neu et al. (2008) also found a large effect size (Cohen's  $d= 2.29$ ) between CFS patients and patients with sleep disorders (sleep apnoea/hypopnoea). The total sample required to detect a large effect size (using effect size convention  $f=0.4$ ) with .8 power, for a one-way ANOVA between three groups, was calculated using G\*power (Faul, Erdfelder, Lang, & Buchner, 2007). This indicated a sample of 22 participants per group.

### **2.2.1. CFS Group**

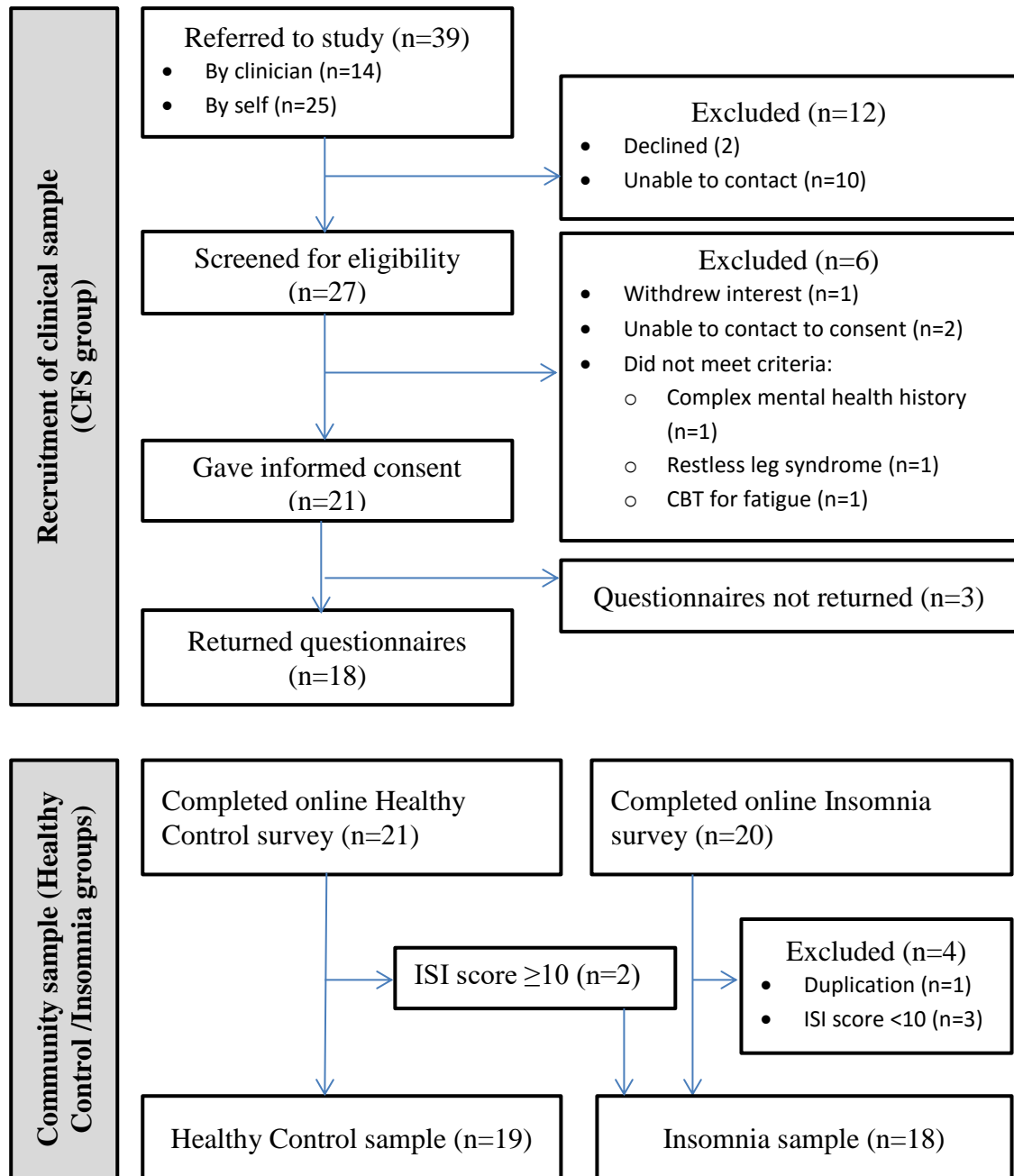
Patients with CFS were invited to participate either by their clinician during routine appointments or by the lead researcher during psycho-educational groups. Potential participants were contacted by telephone and screened against the eligibility criteria. In addition to the above criteria, CFS participants were required to have a clinical diagnosis of CFS and no other significant physical or mental health conditions that might account for their fatigue. To reflect the clinical population, participants with a co-morbid diagnosis of Fibromyalgia ( $n=4$ ) were included, as were participants who reported mild mental health problems that were being managed in primary care (e.g. depression or anxiety;  $n=9$ ). After confirming eligibility, participants were asked to

complete a consent form and return the questionnaire pack, either by post or online. The final CFS sample consisted of 18 participants.

### *2.2.2. Insomnia Group and Healthy Control Group*

For the Insomnia and Healthy Control groups, participants were asked to confirm that they met the study's core eligibility criteria, and additionally to confirm they did not have any significant physical or mental health problems. Participants were then invited to complete an online consent form and directed to the relevant survey. Participants were directed to complete the 'Insomnia' survey if they experienced problems falling asleep, staying asleep or waking early which impacted on their daily life, or to complete the 'Healthy Control' survey if they considered themselves to have no problems with their sleep.

The presence or absence of insomnia was corroborated using the Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001). A cut-off of 10 on this measure suggests insomnia in community samples (Morin, Belleville, Bédard, & Ivers, 2011), therefore participants who self-selected into the Insomnia group but scored below 10 were excluded (n=3). Participants who completed the Healthy Control survey but scored 10 or above were reallocated to the Insomnia group (n=2). One participant completed the Insomnia survey twice (as identified by contact details), therefore the data set with the greatest number of missing items was excluded. The final Insomnia sample consisted of 18 participants, and the final Healthy Control sample of 19 participants.



**Figure 3: CONSORT flow diagram**

### 2.3.Measures

Self-report questionnaires were used to assess the psychological wellbeing and subjective sleep characteristics of the groups, and to assess various cognitive factors associated with CFS and insomnia. The measures were completed independently by participants in their own time. All measures used (with the exception of the *Beliefs*

about *Fatigue Scale*, see below) were previous validated, with good internal consistencies and established cut-offs.

### 2.3.1. General Psychological Characteristics

General psychological wellbeing was assessed using the 14-item *Hospital Anxiety and Depression Scale* (HADS; Zigmond & Snaith, 1983), a widely used measure for screening depression (HADS-D) and anxiety (HADS-A) in medical settings. Both subscales have adequate test-retest reliability (both  $r > 0.7$ ; see Herrmann, 1996) and good internal consistency (mean  $\alpha = 0.83$  for depression,  $\alpha = 0.82$  for anxiety; see Bjelland, Dahl, Haug, & Neckelmann, 2002). McCue, Martin, Buchanan, Rodgers, and Scholey (2003) found good internal reliability for the anxiety ( $\alpha = 0.86$ ) and depression ( $\alpha = 0.81$ ) subscales in a sample with CFS. In the CFS and Insomnia groups only, participants' functional impairment was assessed using the 5-item *Work and Social Adjustment Scale* (WSAS; Mundt, 2002). The WSAS has demonstrated excellent internal consistency ( $\alpha = 0.91$ ) and test-retest reliability ( $r = 0.99$ ) in a clinical sample with insomnia, with a cut-off of  $\geq 17$  discriminating sub-clinical from clinical insomnia (88% sensitivity and 78% specificity; Jansson-Fröjmark, 2014). The WSAS has also demonstrated good internal consistency in CFS samples (Cella, White, Sharpe, & Chalder, 2013).

The 15-item *Penn State Worry Questionnaire* (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) was used to evaluate participants' tendency to worry generally (e.g. "*I am always worrying about something*"). The measure has good internal consistency ( $\alpha = 0.93$ ) and test-retest reliability ( $r = 0.92$ ; Meyer et al., 1990). The PSWQ has been used in previous insomnia research and has been found to differentiate primary insomnia from pain-related insomnia (Tang, Goodchild, Hester, & Salkovskis, 2012). The 14-item *Short Health Anxiety Inventory* (SHAI; Salkovskis, Rimes, Warwick, & Clark, 2002) was used to evaluate anxiety surrounding illness and somatic symptoms. A recent meta-analysis concluded that the SHAI demonstrates good internal consistency, ( $\alpha = 0.74-0.96$ ) and adequate test-retest reliability ( $r = 0.87$ ; Alberts, Hadjistavropoulos, Jones, & Sharpe, 2013). Elevated scores on the SHAI have been identified across various medical settings (Tyrer et al., 2011).

### 2.3.2. *Sleep and Fatigue Symptoms*

The presence of insomnia was screened using the *Insomnia Severity Index* (ISI; Bastien et al., 2001), a brief 7-item scale validated against diagnostic criteria for clinical insomnia. The ISI has been extensively used in insomnia research, including groups with insomnia secondary to physical health conditions (see Omachi, 2011). It has good internal consistency (Cronbach's  $\alpha = 0.74-0.78$ ), and concurrent validity with other insomnia measures. Morin et al. (2011) suggest that a cut-off of  $\geq 10$  is optimal for identifying insomnia in community samples with 86.1% sensitivity and 87.7% specificity. The ISI was used to define the Insomnia and Healthy Control groups and to compare insomnia severity between all groups.

Fatigue severity was assessed using the 11-item *Chalder Fatigue Scale* (ChalderFS; Chalder et al., 1993). This is a reliable measure of fatigue with high internal consistency (Chalder et al., 1993), which is commonly used in clinical practice and has been validated in a CFS population (Morris, Wearden, & Mullis, 1998). Items include, for example, “do you need to rest more [than usual]?” and “do you have less strength in your muscles [than usual]?”. Daytime levels of sleepiness were assessed using the 8-item *Epworth Sleepiness Scale* (ESS; Johns, 1991, 1992), a valid and reliable measure of fatigue that has been extensively used in research with both insomnia and CFS populations (e.g. Neu et al., 2008). This scale asks respondents to indicate how likely they would be to fall asleep in different situations, such as “watching television” and “sitting and talking to someone”.

The 18-item *Pittsburgh Sleep Quality Index* (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) was used to provide a more detailed comparison of perceived sleep quality between groups than the ISI, with seven component scores including sleep onset latency, sleep efficiency and sleep disturbance. The scale has good internal consistency ( $\alpha=0.83$ ) and test-retest reliability ( $r=0.85$ ). The PSQI has been widely used to assess sleep quality in populations with physical health conditions, including CFS (e.g. Neu et al., 2007).

### 2.3.3. *Cognitions related to Sleep and Fatigue*

The widely used 16-item *Dysfunctional Beliefs and Attitudes about Sleep scale* (DBAS-16; Morin, Vallières, & Ivers, 2007) was used to evaluate sleep-related cognitions known to maintain insomnia. The DBAS-16 has adequate internal

consistency ( $\alpha=0.77-0.79$ ) and test-retest reliability ( $r=0.83$ ; Morin et al., 2007), and has been found to be reliable and valid across a range of insomnia groups (Carney, Edinger, et al., 2010). The scale asks respondents to indicate the extent to which they agree with statements relating to unhelpful beliefs about sleep and negative consequences of poor sleep, such as *“I need 8 hours of sleep to feel refreshed and function well during the day”*.

No previously validated measures could be identified that evaluate fatigue-related cognitions. Therefore a 15-item ***Beliefs about Fatigue Scale*** (BAFS; see **Appendix C**) was developed for the present study, using the same response format as the DBAS-16. Items on the BAFS were derived from themes identified in qualitative literature on fatigue-related beliefs in CFS patients (see Deale, Chalder, & Wessely, 1998; Surawy et al., 1995), and adapted items from the DBAS-16. Consistent with cognitive behavioural theory of the maintenance of CFS, items related to potentially unhelpful beliefs about the negative consequences of activity and fatigue, and somatic attributions for fatigue, for example *“doing less activity than usual helps to improve my fatigue”*, and *“I avoid or cancel plans when my fatigue is bad”*.

The 10-item ***Anxiety and Preoccupation about Sleep Questionnaire*** (APSQ; Tang & Harvey, 2004) was used to evaluate sleep-related worry (e.g. *“I worry about my loss of control over sleep”*). This scale has been found to have good internal consistency ( $\alpha=0.86-0.93$ ) and to discriminate well between good sleepers, poor sleepers, and people with insomnia (Jansson-Frojmark, Harvey, Lundh, Norell-Clarke, & Linton, 2011). The 10-item ***Sleep Anticipatory Anxiety Questionnaire*** (SAAQ; Bootzin, Shoham, & Kuo, 1994) was used to evaluate pre-sleep cognitions (e.g., *“I worry that I won’t be able to fall asleep”*) and pre-sleep somatic experiences (e.g. *“I become short of breath”*). This scale has high reliability and differentiates people with insomnia from the general population.

#### 2.3.4. *Additional measures related to CFS and Insomnia:*

Selected subscales from the ***Frost Multidimensional Perfectionism Scale*** (Frost, Marten, Lahart, & Rosenblate, 1990) were used to form a 20-item scale; the 9-item Concern over Mistakes subscale (e.g. *“People will probably think less of me if I make a mistake”*), 4-item Doubts about Actions subscale (e.g. *“It takes me a long time to do something ‘right’”*) and 7-item Personal Standards subscale (e.g. *“It is important to me*

*that I be thorough and competent in everything that I do*”). All three subscales have adequate internal consistency ( $\alpha=0.77-0.88$ ; Frost et al., 1990). Finally, the 12-item ***Beliefs about Emotions Scale*** (BES; Rimes & Chalder, 2010) was used to evaluate unhelpful beliefs about emotional experiences (e.g. *“To be acceptable to others, I must keep any difficulties or negative feelings to myself”*). This measure has good internal consistency ( $\alpha=0.91$ ). The BES has been found to differentiate patients with CFS from healthy controls and to be sensitive to change following CBT intervention (Rimes & Chalder, 2010).

#### **2.4. Data Analysis**

Missing data items ( $n=13$ ) were discussed with the two academic supervisors, who were blind to group allocation. It was agreed to impute missing values with subscale modes for the PSQI ( $n=1$ ), HADS ( $n=1$ ) and SAAQ ( $n=3$ ), and with scale modes for the ESS ( $n=2$ ), HAI ( $n=3$ ), DBAS-16 ( $n=1$ ), APSQ ( $n=1$ ) and BAE ( $n=1$ ).

The three groups were compared for demographic characteristics using a one-way ANOVA for age and Chi-Square analyses or Fisher’s Exact test for categorical variables (sex, ethnicity, marital status, employment status, household income, and medication use). Between-group analyses were also conducted on the measures of general psychological characteristics: depression (HAD-D), anxiety (HADS-A), worry (PSWQ) and health anxiety (HAI), and functional impairment (WSAS).

The primary analysis focussed on whether sleep disturbance and fatigue symptoms were comparable between CFS and insomnia. This was evaluated by group comparisons of mean scores on the ISI, PSQI, ChalderFS, and ESS, using one-way ANOVAs. The secondary analysis was of cognitions about sleep and fatigue, with one way ANOVAS on the DBAS-16, BAFS, APSQ and SAAQ. Additionally, mixed ANOVAs were used to test for any group x belief (DBAS vs. BAFS) interaction, and any group x SAAQ subscale (somatic vs. cognitive) interaction. The relationships between beliefs about sleep/fatigue and the severity of fatigue (ChalderFS) or insomnia (ISI) were looked at using Pearson’s correlations. Additional analyses were conducted to compare groups in terms of vulnerability factors previously identified in CFS and insomnia (i.e. Perfectionism, BAE). Throughout, post-hoc analyses were performed using Fisher’s Least Significant Difference (LSD) test where homogeneity of variance assumptions were met, or using Dunnett’s T3 where assumptions were not met.



### 3. Results

#### 3.1. Demographic Characteristics

Demographic characteristics of the groups are presented in **Table 12**. There were no significant differences between groups in terms of age, sex, ethnicity or marital status. However, significant differences were apparent in employment status, household income, education level and medication use. The CFS group were less likely to be in full-time employment and more likely to report a low household income. A majority of the Insomnia and Healthy Control participants were educated to university degree level, compared to half of the CFS group. All participants reported at least secondary school qualifications. Regular medication use was more frequent in the CFS group, followed by the Insomnia group then Healthy Controls.

**Table 12:** Sample demographics

Participant Demographics	CFS	Insomnia	Healthy Control	ANOVA/ Fisher's Exact Test (FET)
Age	<i>M</i> 41.94 <i>SD</i> 10.61	<i>M</i> 37.89 <i>SD</i> 12.40	<i>M</i> 37.16 <i>SD</i> 12.23	$F_{(2,52)}=0.87, p>.05$
Sex (% female)	88.9	83.3	84.2	FET: $p>.05$
Ethnicity (% white)	94.5	94.1	100	FET: $p>.05$
Marital Status (% married)	72.2	66.7	94.7	$\chi^2_{(2, N=55)}=3.37, p>.05$
Employment status (% full-time)	16.7	66.7	78.9	$\chi^2_{(2, N=55)}=16.05, p<.001$
Household income (% $\geq$ £25,000)	50.0	93.8	94.4	FET: $p<.01$
Education level (% university degree)	50.0	83.3	100.0	FET: $p<.001$
Regular medication use (% yes)	77.8	33.3	15.8	$\chi^2_{(2, N=55)}=15.39, p<.001$

### 3.2. General Psychological Characteristics

Using one-way ANOVAs, significant main effects were found between groups on the HADS-D ( $F_{(2,52)}= 34.06, p<.001$ ), HADS-A ( $F_{(2,52)}=8.47, p<.05$ ), PSWQ ( $F_{(2,52)}=6.96, p<.01$ ) and HAI ( $F_{(2,52)}=9.28, p<.001$ ). Homogeneity of variance assumptions were met for the PSWQ but not the HADS-D, HADS-A or HAI.

Mean scores and standard deviations are presented in **Table 13**. No significant differences were found between the CFS and Insomnia groups in terms of depression (HADS-D), general anxiety (HADS-A), worry (PSWQ) or health anxiety (HAI; all  $p>.05$ ). The Healthy Control group had significantly lower HADS-D score compared to both the CFS and Insomnia groups (both  $p<.001$ ). Similarly, on the HADS-A and PSWQ, the Healthy Control group scored significantly lower than the CFS (both  $p<.01$ ) and Insomnia (both  $p<.05$ ) groups. On the HAI, the Healthy Control group scored significantly lower than the CFS group ( $p<.001$ ), but not the Insomnia groups ( $p>.05$ ). An independent samples t-test was used to compare mean scores on the WSAS between the Insomnia and CFS groups. The CFS group showed significantly higher work and social impairment than the Insomnia group ( $t_{(32)}=6.24, p<.001$ ).

**Table 13:** Scores on general psychological characteristic measures

Measure	CFS <i>M (SD)</i>	Insomnia <i>M (SD)</i>	Healthy Control <i>M (SD)</i>
HADS-D	9.33 (3.22) <sup>a</sup>	6.39 (3.94) <sup>a</sup>	1.21 (1.48) <sup>b</sup>
HADS-A	9.44 (4.68) <sup>a</sup>	7.94 (4.68) <sup>a</sup>	4.05 (2.78) <sup>b</sup>
PSWQ	55.72 (15.19) <sup>a</sup>	54.06 (15.10) <sup>a</sup>	39.58 (13.31) <sup>b</sup>
HAI	16.26 (5.70) <sup>a</sup>	11.78 (7.87) <sup>ab</sup>	7.68 (4.14) <sup>b</sup>
WSAS	29.58 (5.99) <sup>a</sup>	16.94 (5.79) <sup>b</sup>	NA

<sup>a,b</sup> Values with the same superscript are not significantly different

### 3.3. Primary Analyses: Sleep and Fatigue Symptoms

Mean scores on sleep and fatigue measures are presented in **Table 14**. From one-way ANOVAs, significant main effects were found for the ISI ( $F_{(2,52)}=42.41, p<.001$ ), ChalderFS ( $F_{(2,52)}=46.88, p<.001$ ) and ESS ( $F_{(2,52)}=10.64, p<.001$ ). Homogeneity of variance assumptions were not met for ISI or ESS.

**Table 14:** Scores on sleep and fatigue measures

Measure		CFS <i>M (SD)</i>	Insomnia <i>M (SD)</i>	Healthy Control <i>M (SD)</i>
ISI <sup>1</sup>		13.67 (7.11) <sup>a</sup>	15.56 (3.29) <sup>a</sup>	2.53 (2.22) <sup>b</sup>
Chalder FS		27.78 (4.94) <sup>a</sup>	20.06 (4.65) <sup>b</sup>	13.11 (4.23) <sup>c</sup>
ESS		12.28 (6.01) <sup>a</sup>	8.78 (5.29) <sup>a</sup>	4.68 (3.40) <sup>b</sup>
PSQI Component	Sleep Duration	1.06 (1.16) <sup>a</sup>	1.72 (1.18) <sup>a</sup>	0.26 (0.56) <sup>b</sup>
	Sleep Latency	2.06 (1.00) <sup>a</sup>	1.67 (1.33) <sup>a</sup>	0.68 (0.82) <sup>b</sup>
	Sleep Efficiency	1.78 (1.22) <sup>a</sup>	2.06 (1.16) <sup>a</sup>	0.21 (0.42) <sup>b</sup>
	Sleep Disturbance	1.67 (0.49) <sup>a</sup>	1.50 (0.51) <sup>a</sup>	1.11 (0.32) <sup>b</sup>
	Medication Use	1.22 (1.48) <sup>a</sup>	0.44 (0.78) <sup>ab</sup>	0.11 (0.46) <sup>b</sup>
	Daytime Dysfunction	1.89 (0.83) <sup>a</sup>	1.83 (0.79) <sup>a</sup>	0.74 (0.73) <sup>b</sup>
	Subjective Sleep Quality	1.78 (1.06) <sup>a</sup>	2.06 (0.41) <sup>a</sup>	0.47 (0.51) <sup>b</sup>
PSQI Total		11.44 (4.41) <sup>a</sup>	11.28 (3.82) <sup>a</sup>	3.58 (2.46) <sup>b</sup>

<sup>1</sup>72% of the CFS sample scored above clinical cut-off for insomnia on the ISI ( $\geq 10$ ).

<sup>a,b,c</sup> Values with the same superscript are not significantly different

No significant differences were found between the Insomnia and CFS groups in terms of insomnia (ISI) or sleepiness severity (ESS; both  $p > .05$ ). Insomnia severity on the ISI was significantly lower in the Healthy Control group than the CFS group ( $p < .001$ ) and Insomnia group ( $p < .001$ ). Similarly, Healthy Controls scored significantly lower than both the CFS ( $p < .001$ ) and Insomnia ( $p < .05$ ) groups on the ESS. As anticipated, the CFS group had significantly higher fatigue scores on the ChalderFS than the Insomnia group ( $p < .001$ ), who in turn reported significantly higher fatigue than Healthy Controls ( $p < .001$ ).

To further investigate self-reported sleep characteristics, one-way ANOVAs were used to test for between-group differences on the mean total PSQI score and each of the seven component scores (see **Table 10**). Higher scores on all variables indicate greater dysfunction or dissatisfaction. Due to multiple comparisons being made using this measure, a Bonferroni correction was used, indicating a significance level of  $\alpha = .006$ .

Significant main effects were found for all PSQI variables: sleep duration ( $F_{(2,52)}=9.84$ ,  $p<.001$ ), sleep latency ( $F_{(2,52)}=8.18$ ,  $p<.006$ ), sleep efficiency ( $F_{(2,52)}=18.73$ ,  $p<.001$ ), sleep disturbance ( $F_{(2,52)}=7.81$ ,  $p<.006$ ), medication use ( $F_{(2,52)}=6.10$ ,  $p<.006$ ), daytime dysfunction ( $F_{(2,52)}=12.81$ ,  $p<.001$ ), subjective sleep quality ( $F_{(2,52)}=25.80$ ,  $p<.001$ ) and total PSQI score ( $F_{(2,52)}=28.53$ ,  $p<.001$ ).

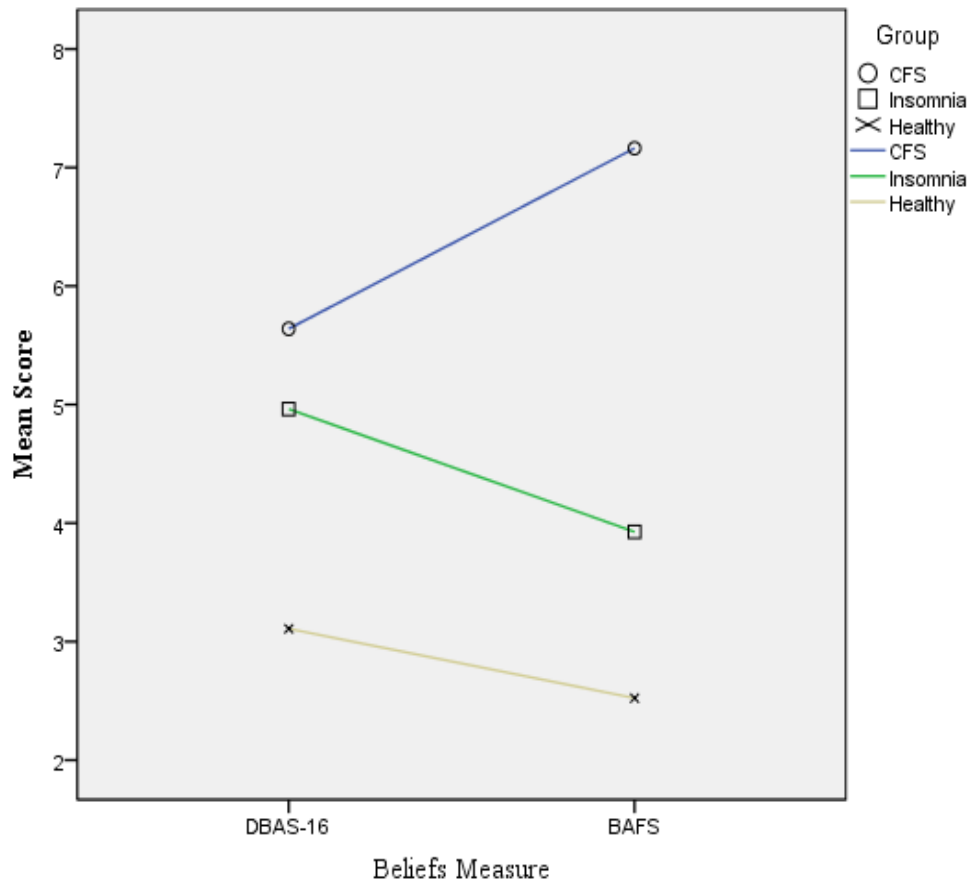
Homogeneity assumptions were not met for the majority of PSQI variables, therefore Dunnett's T3 was used for post-hoc analyses. No significant differences were found between the CFS and Insomnia groups on any of the PSQI variables (all  $p>.05$ ). Both groups scored significantly higher than Healthy Controls on all PSQI variables (all  $p<.05$ ), with the exception of medication use, for which only the CFS groups was significantly higher than Controls ( $p<.05$ ).

### **3.4. Secondary Analyses: Cognitions related to Sleep and Fatigue**

#### **3.4.1. Beliefs about Sleep and Fatigue**

As it was a newly developed measure, the BAFS was analysed for reliability using the data from the whole sample ( $N=55$ ). The internal consistency of the scale was found to be excellent (Cronbach's  $\alpha=0.94$ ).

A repeated measures ANOVA was performed with 'group' as a between subjects factor and belief measure (DBAS-16 and BAFS) as a within-subjects factor. There was no main effect of belief ( $F_{(1,52)}=0.36$ ,  $p>.05$ ), indicating no overall differences between levels of dysfunctional beliefs about sleep and fatigue across the sample as a whole. A main effect of group was found ( $F_{(2,52)}=35.22$ ,  $p<.001$ ), and there was evidence of a significant belief x group interaction ( $F_{(2,52)}=21.18$ ,  $p<.001$ ). See **Figure 4**.



**Figure 4:** Group  $\times$  Belief interaction

One-way ANOVAs were then used as simple main effects analyses of the group differences on the DBAS-16 and BAFS separately. Homogeneity of variance assumptions were met. Significant main effects were found for both the DBAS-16 ( $F_{(2,52)}=14.98, p<.001$ ) and BAFS ( $F_{(2, 52)}=50.84, p<.001$ ). Post-hoc analyses showed no significant difference in DBAS-16 scores between the CFS group and Insomnia group (CFS:  $M=5.64, SD=1.38$ ; Insomnia:  $M=4.96, SD=1.74$ ;  $p>.05$ ), though both were higher than Healthy Controls ( $M=3.11, SD=1.23$ ; both  $p<.001$ )<sup>1</sup>. On the BAFS, significant differences were found between all groups. The CFS group reported higher mean beliefs about fatigue compared to the Insomnia group (CFS:  $M=7.16, SD=1.24$ ; Insomnia:

<sup>1</sup> Due to an error in administration of the DBAS-16, responses were recorded on a 1-10 scale instead of the usual 0-10 scale. To facilitate comparison with other studies, rescaled mean scores for each group are presented below, calculated using the formula  $(x-1)*1.111$ :

- CFS:  $M=5.16$
- Insomnia:  $M=4.40$
- Healthy Control:  $M=2.34$

$M=3.93$ ;  $SD=1.82$ ;  $p<.001$ ) and Healthy Controls ( $M=2.52$ ,  $SD=1.16$ ;  $p<.001$ ). The Insomnia group also scored significantly higher than Healthy Controls ( $p<.01$ ).

Paired-samples t-tests were used to look at the pattern of group differences in sleep and fatigue beliefs. In the CFS group, the mean BAFS score was significantly higher than the mean DBAS score ( $t_{(17)}=-4.95$ ,  $p<.001$ ). By contrast, the mean DBAS score was significantly higher than the mean BAFS score in both the Insomnia ( $t_{(17)}=2.81$ ,  $p<.05$ ) and Healthy Control ( $t_{(18)}=3.08$ ,  $p<.01$ ) groups.

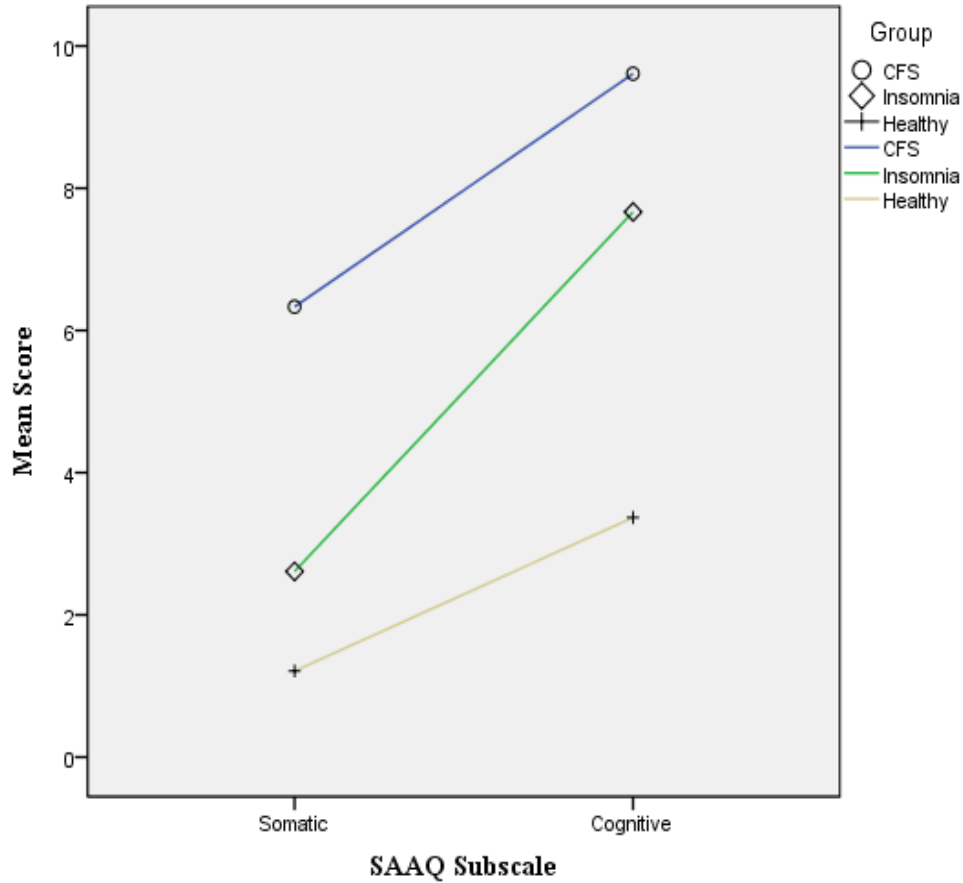
#### 3.4.2. *Relationships between Cognitive Measures and Sleep and Fatigue*

Pearson's correlations were used to look at relationships between fatigue and insomnia symptom severity and scores on the DBAS-16 and BAFS, for the CFS and Insomnia groups separately. In the CFS group, significant positive correlations were found between insomnia severity (ISI score) and DBAS-16 score ( $r_{(16)}=.517$ ,  $p<.05$ ), and between fatigue severity (ChalderFS score) and DBAS-16 scores ( $r_{(16)}=.614$ ,  $p<.01$ ). No relationships were found between either insomnia or fatigue severity and beliefs about fatigue (BAFS). In the Insomnia group, a significant positive relationship was found between insomnia severity and DBAS-16 scores ( $r_{(16)}=.470$ ,  $p<.05$ ). No relationships were found between fatigue severity and the DBAS-16, or between fatigue or insomnia severity and the BAFS. Having dysfunctional beliefs about sleep was associated with higher insomnia severity in both the CFS and Insomnia groups, and with higher fatigue severity in the CFS group only.

#### 3.4.3. *Sleep-Related Anxiety*

A one-way ANOVA revealed a significant between-group effect on the Anxiety and Preoccupation about Sleep Questionnaire (APSQ;  $F_{(2,52)}=18.38$ ,  $p<.001$ ). The homogeneity of variance assumption was met. There was no significant difference between the CFS and Insomnia groups (CFS/MS:  $M=64.61$ ,  $SD=22.18$ ; Insomnia:  $M=53.22$ ,  $SD=23.24$ ,  $p>.05$ ). Both groups reported significantly higher anxious cognitions about sleep than Healthy Controls ( $M=23.63$ ,  $SD=18.27$ , both  $p<.001$ ).

A repeated measures ANOVA was used to look at differences in the cognitive and somatic subscales of the Sleep Anticipatory Anxiety Questionnaire (SAAQ) between groups. This revealed a significant main effect of subscale ( $F_{(1,52)}=62.97$ ,  $p<.001$ ), a significant main effect of group ( $F_{(2,52)}=16.72$ ,  $p<.001$ ) and a significant subscale x group interaction ( $F_{(2,52)}=3.68$ ,  $p<.05$ ). See **Figure 5**.



**Figure 5:** *Group x SAAQ subscale interaction*

One-way ANOVAs were used to conduct simple main effects analyses of the group differences in pre-sleep cognitive and somatic signs of anxiety. These revealed significant between-group differences in cognitive ( $F_{(2,52)}=11.71, p<.001$ ) and somatic ( $F_{(2,52)}=18.37, p<.001$ ) subscales. The homogeneity of variance assumption was met for the cognitive subscale but not the somatic subscale.

For the cognitive subscale, there was no significant difference between the CFS group and Insomnia group (CFS:  $M=9.61, SD=3.84$ ; Insomnia:  $M=7.67, SD=4.56$ ;  $p>.05$ ). Both groups reported equally elevated levels of cognition about sleep during the pre-sleep period, which were higher than reported by Healthy Controls ( $M=3.37, SD=3.63$ ; both  $p<.01$ ). For the somatic subscale, the CFS group scored significantly higher than the Insomnia group (CFS:  $M=6.33, SD=3.43$ ; Insomnia:  $M=2.61, SD=2.30$ ;  $p<.01$ ) and the Healthy Control group ( $M=1.21, SD=2.15$ ;  $p<.001$ ). No significant difference was found between the Insomnia and Healthy Control groups ( $p>.05$ ), therefore the CFS group alone reported elevated pre-sleep somatic experiences.

### *3.5. Additional measures related to CFS and Insomnia*

One-way ANOVAs were used to compare mean scores between groups on the beliefs about emotions (BAE) scale and 20-item Perfectionism scale. Homogeneity of variance assumptions were met. Significant main effects were found between groups for both BAE ( $F_{(2,52)}=5.61, p<.01$ ) and Perfectionism ( $F_{(2,52)}=4.50, p<.05$ ).

Post-hoc analyses indicated that there was no significant difference in BAE between the CFS and Insomnia groups (CFS:  $M=40.56, SD=14.57$ ; Insomnia:  $M=36.72, SD=15.61$ ;  $p>.05$ ). Both the CFS ( $p<.01$ ) and Insomnia ( $p<.05$ ) groups scored significantly higher than Healthy Controls ( $M=24.85, SD=14.61$ ). Similarly, no significant difference in perfectionism was found between the CFS and Insomnia groups (CFS:  $M=63.44, SD=15.16$ ; Insomnia:  $M=64.67, SD=11.87$ ;  $p>.05$ ), but both CFS ( $p<.05$ ) and Insomnia ( $p<.01$ ) groups scored significantly higher than Controls ( $M=52.79, SD=12.7$ ).

## **4. Discussion**

### *4.1. Overview*

The aim of the present study was to directly compare the subjective sleep experiences of those with CFS versus insomnia, including self-report of sleep and fatigue symptoms, as well as cognitions related to these processes. While they differed from healthy controls, these two groups were comparable on most variables assessed, including depression, anxiety, sleepiness, insomnia severity and cognitions about sleep. The CFS and insomnia groups differed only in terms of functional impairment, fatigue severity, cognitions about fatigue and somatic symptoms in the pre-sleep period, with the CFS group scoring higher.

### *4.2. Similarities between CFS and Insomnia*

In line with previous research, the findings of the present study suggest that self-reported disturbed sleep is a significant problem in the CFS population (Jackson & Bruck, 2012; Mariman, Delesie, et al., 2013; Mariman, Vogelaers, et al., 2013). By directly comparing CFS and insomnia samples we found that levels of self-reported insomnia symptoms are comparable in those with CFS versus insomnia. The findings further suggest similarities in key cognitive processes that are known to maintain poor sleep and insomnia (see Carney et al., 2010; Espie et al., 2006; Harvey, 2002; Harvey et al., 2005). These included comparably elevated levels of unhelpful repetitive thinking in



the pre-sleep period, and unhelpful beliefs about sleep and the consequences of not sleeping (e.g. *“Without an adequate night's sleep, I can hardly function the next day”*). In both the insomnia and CFS groups, elevated levels of dysfunctional beliefs about sleep were associated with increased insomnia severity, suggesting that the relationship between sleep-related cognitions and sleep disturbance is similar in both populations.

While it was anticipated that perfectionism would be elevated in both groups due to previous findings (Kempke et al., 2011; Lundh et al., 1994; Vincent & Walker, 2000), research had yet to directly compare whether this feature would be more problematic in either CFS or insomnia. The current findings suggested that perfectionistic traits were equally, although only slightly, elevated in both groups compared to controls. An unexpected finding was that people with CFS and people with insomnia did not differ in terms of unhelpful beliefs about emotions. Given the importance placed on this characteristic in cognitive-behavioural models of CFS, it was anticipated that it would show greater specificity in differentiating the groups. However, both groups reported stronger beliefs about emotions compared to controls, suggesting this trait may be equally relevant in insomnia.

#### *4.3. Differences between CFS and Insomnia*

Some notable differences between the CFS and insomnia groups were observed. CFS patients were found to have higher levels of health anxiety than healthy controls, a pattern that was not found with the insomnia group. Those with CFS were also more impaired in their daily functioning than the insomnia group. As might be anticipated, as well as being ‘sleepy’, CFS patients reported higher levels of fatigue than those with insomnia, and had stronger beliefs about the negative consequences of fatigue and activity. Finally, CFS patients reported higher levels of somatic anxiety symptoms in the pre-sleep period compared to people with insomnia, possibly indicating a greater attentional bias to physical changes when trying to initiate sleep. These findings are in line with the cognitive-behavioural theory of CFS (see Knoop et al., 2010), suggesting that people with this condition hold potentially unhelpful beliefs about the consequences of fatigue and activity, and may attend to somatic signs of fatigue and tiredness.

It was interesting to find that fatigue severity in the CFS groups was associated with dysfunctional beliefs about sleep, but not with beliefs about fatigue. The relationship between sleep-related cognitions and fatigue was not found in the insomnia group. This finding could be interpreted in light of the suggestion that individuals with CFS

misinterpret the connection between sleep and fatigue, expecting sleep to improve their fatigue levels (Westcombe & O'Dowd, 2012). Those who experience more severe fatigue might therefore develop stronger beliefs about the importance of sleep and greater anxiety about the consequences of not sleeping. Alternatively, those with stronger dysfunctional beliefs about sleep might be more attentive to signs of tiredness following a poor night's sleep, resulting in a perception of worsened fatigue. The direction of this relationship can only be hypothesised from the current findings, and warrants further investigation.

#### *4.4.Limitations and Future Direction*

Some limitations of the present study in terms of the sample are important to note. The study was slightly underpowered, as power analysis indicated a sample size of 22 participants per group. Replication with a larger sample would therefore be beneficial. Also, the insomnia sample was recruited through community channels. Although a clinical cut-off on a well-validated standardised measure of insomnia was used to define the sample, this does not guarantee that the results would be the same for individuals with insomnia who seek treatment. Replication is therefore needed with a clinical insomnia sample.

The Beliefs About Fatigue Scale (BAFS) was a previously unvalidated measure created for this research, as no measures were identified targeting dysfunctional beliefs about fatigue. The measure was designed based on items from the DBAS-16 and the existing qualitative literature, and showed good internal consistency in the current sample. However there is a need for replication and further testing of the psychometric properties of the BAFS using larger samples, particularly as in the current study this measure was not found to relate to fatigue severity. Further psychometric analysis will need to examine the test-retest reliability of the BAFS when re-administered at different time points, and look at the validity of the construct of unhelpful beliefs about fatigue by seeing how this measure relates to other variables; for example, does having unhelpful beliefs about fatigue predict behavioural maintenance factors for CFS, such as activity avoidance? It would also be interesting to conduct a factor analysis to identify whether the BAFS captures more than one construct (Barker, Pistrang, & Elliot, 2002).

A further limitation of the present study was the use of self-report measures only. Objective measures of sleep such as polysomnography would have provided an indication of whether there were actual differences in sleep quality between the groups.

That said, this line of research has recently been investigated by other researchers (Neu et al., in press), and the focus of our research was specifically the subjective sleep experience and associated psychological factors. To expand on the current findings, future research could conduct more in-depth comparisons of behavioural maintaining factors for insomnia and CFS (e.g. activity avoidance), as the current study primarily investigated cognitive maintaining factors.

#### *4.5. Summary and Clinical Implications*

To our knowledge, this is the first study to directly compare cognitive processes related to the subjective sleep and fatigue experiences of those with CFS and insomnia. Similarities were found in self-reported insomnia symptoms and cognitions known to maintain insomnia, including dysfunctional beliefs about sleep and pre-sleep cognitive arousal. Of note, such cognitions are those that are typically targeted in cognitive-behavioural treatment for insomnia (CBT-I). The current results therefore suggest that it may be appropriate to use a transdiagnostic approach to addressing sleep problems in CFS. Recent trials have looked at the use of CBT-I approaches for sleep in different physical health conditions, such as chronic pain (Tang, Goodchild, & Salkovskis, 2012) and fibromyalgia (Martínez et al., 2014), with promising outcomes. It is therefore hoped that the current findings may contribute to similar developments in the field of CFS. The present study also found, as expected, that fatigue levels, negative beliefs about fatigue and somatic complaints were elevated in CFS compared to insomnia. Therefore it is important for clinicians to remain cognisant of the presence of these types of cognition through the course of treatment.

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## **Executive Summary**

### **Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome and Insomnia**

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June 2015

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**Internal Supervisors:** Professor Paul Salkovskis & Dr Rachel Hiller

**External Supervisor:** Dr Hazel O'Dowd

**Word Count:** 652

## **Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome and Insomnia**

### **Background**

Sleep disturbances are a common feature of Chronic Fatigue Syndrome (CFS) and patients often report feeling unrefreshed on waking. However, research that has looked at the sleep patterns of people with CFS using objective recording methods has not found evidence for a problem with sleep. Similar findings occur in people who have insomnia; they report poor quality sleep, but the objective evidence does not confirm this. Therefore there seems to be a misperception about sleep quality in both conditions. Psychological models of both CFS and insomnia include some of the same vulnerability factors (e.g. perfectionism) and some similar maintaining factors such as unhelpful cognitive (thinking) processes. People with insomnia tend to pay attention to signs of tiredness, have unhelpful repetitive thoughts while trying to fall asleep (e.g. worrying about not sleeping), and hold unhelpful beliefs about their sleep (e.g. *“Without an adequate night's sleep, I can hardly function the next day”*). People with CFS tend to pay attention to physical symptoms and to hold negative beliefs about their fatigue (e.g. that fatigue will negatively affect performance).

Although there are common features, psychological factors relating to sleep and fatigue in people with CFS versus insomnia have not been compared before. This research study looked at what the similarities and differences are between people with CFS and people with insomnia, in terms of their self-reported sleep and fatigue symptoms, their thoughts about sleep and fatigue, and other psychological factors.

### **What we did**

Patients with CFS (n=18) were recruited through specialist NHS services. People with insomnia (n=18) and healthy volunteers (n=19) were recruited via the internet. All of the participants gave informed consent to take part in the study and then completed a set of questionnaires. These asked about: depression and anxiety; sleep quality; sleepiness and fatigue symptoms; cognitive processes relating to sleep and fatigue; perfectionism (e.g. *“It is important to me that I be thorough and competent in everything that I do”*) and unhelpful beliefs about emotions (e.g. *“To be acceptable to others, I must keep any*

*difficulties or negative feelings to myself*”). Statistical tests (ANOVAs) were used to see if there were significant differences between the three groups on each of the measures.

## **What we found**

The CFS and Insomnia participants reported similar scores on most of the measures. No significant differences were found in depression, anxiety, worry, insomnia severity, sleep quality, sleepiness, cognitions relating to sleep, perfectionism, or beliefs about emotions. On all of these measures, both groups scored significantly higher than the healthy volunteers. The CFS participants (but not the Insomnia participants) also reported higher levels of anxiety about their health than healthy volunteers. As expected, the CFS group reported higher levels of impairment in their day-to-day lives, worse fatigue symptoms, and stronger beliefs about fatigue (e.g. *“doing less activity than usual helps to improve my fatigue”*) compared to the other groups. Patients with CFS also reported more physical signs of anxiety when trying to fall asleep (e.g. *“I become short of breath”*) compared to both of the other groups.

## **Conclusion**

The study found evidence that the self-reported sleep disturbances in CFS are comparable to those found in people with insomnia as their main problem. Both groups report similar levels of insomnia symptoms, sleep quality and sleepiness. The findings also suggest that the same thinking processes that are known to maintain insomnia are also found in people with CFS. These thinking processes are targeted during cognitive-behavioural therapy for insomnia (CBT-I), therefore our findings suggest that this treatment approach might be helpful for treating sleep disturbances in CFS. We also found some important differences between the groups. Compared to people with insomnia, people with CFS appear more likely to be aware of physical sensations while trying to fall asleep, be anxious about their health, and hold potentially unhelpful beliefs about their fatigue symptoms. It is therefore important for clinicians working with CFS patients to be aware of these factors during treatment.

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# **Connecting Narrative**

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June 2015

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**Internal Supervisor:** Dr Maria Loades

**Word Count:** 2,994

## Connecting Narrative

Through the course of Clinical Psychology training, I have had opportunities to develop a wide range of research skills and to gain experience of the full research process, from the initial brainstorming of ideas to disseminating my findings. This connecting narrative draws together my reflections on these experiences, in relation to the following pieces of work:

- Literature Review: *Overgeneral autobiographical memory and depressive symptoms in older adults: An evaluative review*
- Service Improvement Project (SIP): *An evaluation of psychological service provision in a palliative care setting*
- Main Research Project: *Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome/M.E. and insomnia*
- Case Study 1: *Health anxiety in the context of co-morbid anxiety and trauma*
- Case Study 2: *A cognitive behavioural intervention for adjustment to late-onset multiple sclerosis (MS)*
- Case Study 3: *Cognitive behavioural intervention for anxiety in a client with mild intellectual disabilities: What adaptations may be needed to the therapeutic process?*
- Case Study 4: *Engaging an adolescent with chronic selective mutism in a behavioural intervention programme*
- Case Study 5: *Enhanced cognitive behaviour therapy (CBT-E) for bulimia nervosa in a client with co-morbid obesity*

My topic choices for each of these projects and case studies have been guided by my areas of clinical interest. I have a particular interest in Clinical Health Psychology, which was established prior to training and has remained a long-term focus for my career. As such, physical health is a strong theme that connects my Service Improvement Project, Main Research Project, and case studies 1, 2 and 5. In order for research to remain clinically relevant, I believe it is important to evaluate established cognitive behavioural models and treatment approaches in the context of different client groups and unusual or complex presentations. In line with this interest, cognitive-behavioural theory and transdiagnostic approaches connect my Literature Review, Main Research Project, and is a theme running through all five case studies.

## **Literature Review**

### *Choice of Topic*

I found it difficult to choose a subject for my Literature Review, as the potential scope was so wide. At the time of needing to decide on a topic, we were in our Older Adult teaching block and I thought about potential ideas relating to our lectures. Initially I was drawn to an idea around attachment and depression in older adults, however after meeting my supervisor, Dr James Gregory, and discussing current lines of research in depression, it was agreed to look at rumination and overgeneral memory in older adults with depression. I was pleased with this choice of topic as it matched well with my interest in transdiagnostic cognitive processes.

### *Research Process*

Conducting literature searches and screening papers took considerably longer than I had anticipated. I had never previously completed a review on this scale and, although it was an evaluative review, it felt important to me to be thorough and systematic in my methods. In retrospect, this process may have been facilitated by more clearly defining my inclusion and exclusion criteria from the outset. This became more of an iterative process, based on the nature and number of search results I found. Towards the end of screening, it was clear that the number of papers identified was too large to be feasible. After discussing options with my supervisor, I decided to exclude rumination and instead focus the review on overgeneral memory.

From the point of deciding on the final set of included articles, the review progressed more quickly. I enjoyed the opportunity to spend time reading in depth on one topic, and to see patterns of findings emerging across the different studies. Writing up the paper also progressed quickly, facilitated by my supervisor agreeing clear deadlines with me for sections to be written and reviewed.

### *Outcome*

Overall, I felt pleased with the finished result. My review drew together some quite disparate pieces of literature under the same theoretical framework, and provided some clear directions for future research and clinical practice. I feel that I also learned valuable skills in terms of literature review methodology, and have a much better appreciation of the time involved in conducting a good quality literature review.

## **Service Improvement Project**

### *Choice of Topic*

My choice of Service Improvement Project (SIP) was made quite quickly in the first term of training. Dr Anna Lagerdahl contacted our cohort offering the opportunity to conduct a SIP around the clinical psychology service at the Hospice. I was immediately keen to take up this opportunity. I had interests in oncology and palliative care, however for personal reasons felt it would be challenging to work clinically in this area. Conducting my SIP in this field enabled me to gain some experience and knowledge of palliative care practice, while also contributing to improving services for staff and patients. At a first meeting, Anna and I discussed the project as being focused on evaluating the Clinical Psychology service. After further discussion and reading the literature and relevant policies, I expanded the scope to include an evaluation of the wider psychological service being provided by all staff at the hospice and relating this to national guidelines.

### *Ethical Approval*

As it was not an NHS service and I was not collecting data from patients or carers, approval from the Hospice was a simple process of obtaining agreement from the Hospice board. Ethical approval was also required from the University Department of Psychology Ethics Committee. Unfortunately, I was unaware that the Committee did not meet during the summer months. I had hoped to complete data collection during the summer between my first and second years, however this was delayed until the autumn term of my second year while awaiting approval. The Committee asked me to submit final versions of the staff survey and the interview/focus group question schedule. As it was planned to develop the question schedule from the outcome of the questionnaire, it was necessary to submit one application for the questionnaire element of the study, and a later application for the interviews/focus group. This was a useful learning experience in terms of understanding ethical review procedures.

### *Research Process*

Collecting the survey and interview data for my SIP was challenging due to not being physically based within the service and having limited research time. I was therefore quite reliant on my field supervisor for facilitating communication with team leaders, although I was able to arrange and attend meetings to promote the project to different

staff groups. The response rate for the survey was not as high as hoped, possibly due to the difficulties in promoting the project and the relatively short space of time for data collection.

My SIP was the first time I had conducted qualitative research. Transcribing the interviews and focus group took considerably longer than I expected, however I enjoyed this as it allowed me to immerse myself in the data and to think about themes that were emerging. Identifying the final themes was challenging as there were so many potential ways to group the data and interconnections between different themes. Having my internal supervisor, Dr Cathy Dysch, to read the transcripts and discuss themes with was extremely helpful and gave me confidence to make these decisions. I learned that while there is a degree of subjectivity in interpreting qualitative data, this is acceptable as long as you acknowledge and hold an awareness of your position and apply structured methods. I feel that I gained a much better appreciation of qualitative analysis through this project.

### *Outcome*

The response I received when feeding back my findings to the Patient Services Director was very positive. I had not expected the Hospice to make firm plans to implement my recommendations immediately, and felt proud that the hard work I had put into the project was recognised. I received feedback from the Hospice that they felt I had really understood their service, despite not working there, and had made recommendations that were very realistic and relevant. This outcome was extremely rewarding and encourages me to seek opportunities to be involved in service development work in the future.

## **Main Research Project**

### *Choice of Topic*

On starting training, I had no preconceived ideas about my main research topic, other than wanting this to be in a Clinical Health Psychology field. I had hoped to develop an idea through the Research Fair in our first term. However, the Fair was disappointing as it was poorly attended by regional supervisors. I arranged some discussions with regional supervisors about potential projects, however nothing emerged from this. I



therefore arranged a meeting with Professor Paul Salkovskis to brainstorm ideas. Through considering my interests in physical health and transdiagnostic research, the idea for my final project emerged. Paul had previously been involved in research on insomnia in chronic pain, and raised the suggestion of taking a similar approach to CFS. This topic appealed for personal reasons, as a close friend has experienced severe CFS for many years. I felt I therefore had some insight into the condition and would be motivated to work towards contributing to the evidence-base in this field. Meeting with regional Clinical Psychologists who worked in CFS helped to encourage me that the idea would be very relevant to clinical practice. My regional supervisor, Dr Hazel O'Dowd also put me in contact with a service-user, who provided very useful feedback on the proposed study and documentation and how this might be received by patients.

### *Ethical Approval*

The process of gaining approvals for my Main Research Project was probably the most challenging aspect of my training. Developing an initial outline of a project into a detailed protocol to meet the requirements of an NHS Research Ethics Committee and two different NHS Trusts involved numerous drafts, emails and meetings, with delays waiting for responses at every stage. I had thought I was prepared for this due to my previous role as a Clinical Studies Officer, which involved local site set-up for different NHS research projects. However, it proved more challenging than expected, particularly given the limited research time available during the second year of training. Due to the demands on his time as Programme Director, I was not always able to meet with Paul when needed, therefore Dr Rachel Hiller agreed to act as a second internal supervisor at the end of my second year. Having this additional input to review study documents was extremely helpful.

One of the NHS services asked for a number of revisions to the study documentation. As I was keen to have two recruitment sites, I chose to wait for this service to confirm they were happy with the documents before submitting my REC application. In retrospect, it would have been preferable to have sought REC approval earlier on the basis of one recruitment site, and to make amendments later if necessary. The actual process of obtaining REC approval after submitting my application was, fortunately, quite quick as this passed through proportionate review with only minor changes. The Trust R&D processes were relatively smooth for one site, but required some additional effort at another site.

### *Research Process*

Due to the time taken to set up the study, I had only around three months to recruit participants. For the Healthy Control and Insomnia samples, I recruited using social media, and was able to achieve a reasonable sample size quite quickly. For the clinical sample, one of my main sources of recruitment was through attending group programmes run by the North Bristol NHS Trust. This also provided me with opportunities to learn more about clinical approaches to CFS and gain insight into the realities of living with the condition. I was also dependent on referrals from clinicians in the recruiting teams, which was challenging due to not working clinically at these sites. As a clinician, I understand that being asked to recruit for research is an added demand on pressured clinical time, and is not likely to be a high priority. It was therefore difficult to balance my need to drive forward recruitment with not wanting to appear too pushy or demanding. I found that regular email reminders of the approaching deadlines encouraged clinicians to refer, as well as engaging service leads to send out reminders on my behalf.

Due to the short recruitment period, I was unable to obtain the clinical sample I had hoped for. It was originally planned to divide the CFS sample into two groups based on insomnia severity, to enable comparison of cognitive factors between individuals with CFS with and without clinical insomnia. However, only one group was possible. Despite this change, I feel the design as it stands is strong and revealed some interesting findings. Conducting the data analysis was initially overwhelming due to the number of measures used. It was tempting to just start comparing everything! However my supervisors encouraged me to form a clear plan as to the questions we wanted to address, so that the analyses we ran were targeted. Having opportunities to discuss the findings with my supervisors was really helpful to clarify my thinking and shape the final write-up.

### *Outcome*

Due to the nature of my Main Research Project, I had no strong expectations about what the findings might show; whether or not there were differences between the CFS and insomnia groups, the outcome would have been interesting. The final outcome fits well with the existing literature and leads to some interesting research and clinical implications about the nature of the sleep problems reported in CFS. I have not yet had

the opportunity to disseminate the findings to the clinical services involved or to patients, but I look forward to seeing how these are received. While extremely stressful at the time, the difficulties experienced in conducting this project have provided me with useful knowledge about the challenges of conducting NHS-based research, which will prepare me well for future projects.

## **Case Studies**

### *Choice of Topics*

For each of my case studies, I have chosen cases that have an interesting point of difference. As so many clients seen in clinical practice do not precisely ‘fit’ into evidence-based models, I believe it is important to test the generalisability of psychological treatments by evaluating their use with clients with slightly different presentations. This fits with current movements in Clinical Psychology towards transdiagnostic and lifespan approaches to treatment. All of my case studies have therefore included some element of co-morbidity that complicates treatment, or have focused on a client with an unusual presentation for their age group.

### *Research Process*

While identifying suitable cases has been straightforward, I have always felt anxious about approaching clients with the request to write a case report about our work, as I worry they will feel it to be intrusive. I have been surprised at how willing clients have been to consent to this. Once I had decided on a case to write up, I was conscious of the potential for this to impact on my clinical work, for example using additional outcome measures or trying techniques I might not otherwise have used, driven by my research needs rather than clinical need. However, rather than compromising clinical practice, I think that the process of writing a case report has led to higher quality pieces of clinical work, due to the additional reading I have done around the subject and detailed discussions in supervision.

### *Outcome*

I have found producing detailed written accounts of my clinical work to be one of the most useful elements of training. It has provided a direct link between my placement experience and the research and academic aspects of the course. Opening my clinical practice to the scrutiny of course tutors has felt exposing, however I have generally

received very positive feedback. Writing case studies has also encouraged me to apply more rigorous methods to evaluating my clinical work generally and to think more carefully about the evidence-base and rationale for my treatment decisions. This is something I will carry into my wider clinical practice.

## **Reflections and Future Research Plans**

My experience of research throughout the programme has been mixed. Some aspects have been quite stressful and led to a lot of uncertainty, particularly the process of setting up my Main Research Project. It was also very challenging to identify topics for my Main Research Project and Literature Review, as there was some pressure to think of ideas quickly at the beginning of training, when I had relatively little clinical experience and academic knowledge to draw these ideas from. However, other aspects of conducting my research have been really interesting and enjoyable, and I have felt a real sense of reward from the final outcome of all of my projects. After three years of teaching and clinical placements, I have come to see that potential ideas for research are everywhere.

In terms of research skills, training has given me a broad range of experiences to draw on. This has included conducting research in NHS and third sector organisations, using quantitative and qualitative methodologies, conducting literature reviews and single-case experimental designs. I have a better awareness of some of the challenges and obstacles to conducting clinical research, such as the delays inherent in obtaining approvals, and juggling research with competing clinical demands. I understand the importance of negotiating protected time for research and service development activities if I wish to do this as part of a clinical role.

By the end of training, I plan to submit some of my research work for publication to gain experience of the peer-review process and the exposure of disseminating my work more widely. While I envisage my career being primarily clinical rather than academic, I plan to continue to use my research skills in the context of my clinical work. I will seek opportunities to lead on service evaluation and development, and hope to be able to contribute to the evidence base by publishing examples of my clinical practice and small-scale service related projects. Long-term, I will be keen to have ongoing

involvement in research being conducted on the Bath Programme by acting as a supervisor or collaborator for future trainees' research.

## Acknowledgements

Thank you to Professor Paul Salkovskis for your seemingly endless inspiration and enthusiasm for research, and to Dr Rachel Hiller for balancing this so well with your down-to-earth guidance and direction. My main research project could not have come together without either of you. I am grateful to Dr Hazel O'Dowd, the North Bristol NHS Trust CFS/ME team, and the Royal National Hospital for Rheumatic Diseases Fatigue Management Service for their input in shaping the project and their help with identifying participants. Most importantly, thank you to all the people who generously provided their time and participated in the study.

My thanks go to Dr Anna Lagerdahl, Dr Claire Lomax, and Dr Cathy Dysch for their help and guidance at various stages of my Service Improvement Project, and to all of the Hospice staff who welcomed me so positively while working there. For my Literature Review, I am grateful to Dr James Gregory for his ideas, motivation and constructive feedback.

Special thanks go to my Clinical Tutor, Dr Maria Loades, for her efficiency in all things and for providing much-needed support and validation at stressful times. I am also grateful to each of my Clinical Supervisors for their patience, guidance and encouragement. I once heard it said that you adopt parts of every supervisor you have throughout training to shape the Clinical Psychologist you become, and I have found this to be true.

To my fellow trainees, thank you for being there through all of the ups and downs we have shared over the past three years. I will miss your companionship and support. To my parents, thank you for always encouraging me to believe in myself and reach my goals (and for forgiving my extended lack of contact while working towards them). Finally, to Shane, thank you for patiently learning to live with me through all the stress and sleepless nights. I promise we will have our weekends back.

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**Research Portfolio**

**Appendices**

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## **Appendix A: Study quality checklist- Literature Review**

### **Critical Appraisal Journal Article Review Form**

Please tick one column for each item to indicate how well you think it has been addressed.

	<b>Not acceptable</b>	<b>Barely adequate</b>	<b>Adequate</b>	<b>Good</b>
<b>Review of literature</b>				
<b>Design and methodology</b>				
<b>Selection and description of subjects</b>				
<b>Analysis of data</b>				
<b>Presentation of tables and figures</b>				
<b>Discussion of results</b>				
<b>Conclusions and implications</b>				
<b>Summary/Abstract</b>				
<b>Referencing</b>				
<b>Clarity of style and expression</b>				
<b>Sequencing of contents</b>				
<b>Ethical acceptability</b>				
<b>Theoretical importance</b>				
<b>Contribution to knowledge</b>				
<b>Breadth of interest</b>				



## Appendix B: Staff survey- Service Improvement Project

### Evaluation of Psychological Service Provision at the XXX Hospice

#### Staff Questionnaire

*Please read the enclosed Information Sheet and read and sign the Consent Form before completing this questionnaire. If you have any queries, please contact Flora Wilson (Clinical Psychologist in Training) at [fclw20@bath.ac.uk](mailto:fclw20@bath.ac.uk).*

The questionnaire is divided into two sections. Section A comprises questions about any psychological support that you currently provide to patients and carers in your role at the XXX Hospice. Section B asks for your views regarding the Clinical Psychology service provided at the Hospice. Please tick boxes as appropriate and provide any written comments in the spaces provided.

#### Section A

##### About you

**1. What is your professional background?**

Doctor  
Nurse (please specify) .....  
Occupational Therapist  
Physiotherapist  
Social Worker  
Healthcare Assistant/Nursing Assistant  
Other (please specify).....

**2. Which part of the Hospice do you work in?**

Day Hospice  
Inpatient Unit  
Family Support Team  
Therapy Team  
Community/Hospice at Home  
Other (please specify).....

**3. Do you have any formal qualifications in psychological therapies or counselling?**

No  
Yes (please provide details below)

.....

.....

**4. The National Institute for Clinical Excellence (NICE) recommends a four-level model of psychological assessment and intervention in Palliative Care.**

Please read the descriptions of the four levels and answer the questions below:

Level	Group	Assessment	Intervention
<b>1</b>	All health and social care professionals	Recognition of psychological needs	Effective information giving, compassionate communication and general psychological support
<b>2</b>	Health and social care professionals with additional expertise	Screening for psychological distress	Psychological techniques such as problem solving
<b>3</b>	Trained and accredited professionals	Assessed for psychological distress and diagnosis of some psychopathology	Counselling and specific psychological interventions such as anxiety management and solution-focused therapy, delivered according to an explicit theoretical framework
<b>4</b>	Mental health specialists	Diagnosis of psychopathology	Specialist psychological and psychiatric interventions such as psychotherapy, including cognitive behavioural therapy

Guidance on Cancer Services: Improving Supportive and Palliative Care for Patients with Cancer (NICE, 2004)

- a. At which level would you identify yourself as working currently? .....
- b. At which level do you consider you could be working in your role? .....
- c. If there is a difference between your answers to **a.** and **b.**, please provide an explanation below:

.....

.....

**5. How large a part of your role is the delivery of psychological support and/or intervention?**

It is a main focus of my role

It is an integrated part of my routine interactions with patients/carers

It is not a part of my role

**If delivering psychological support and/or intervention is part of your role,** please give an approximate percentage of your working time that is allocated for this.

.....%

**6. a. Have you attended the following training courses? Please tick all that apply.**

National Advanced Communication Skills training  
Level 2 Psychological Skills (4 half-day sessions)

**If not, why is this?**

.....

**b. If you *have* attended the above training, approximately how often do you access supervision with a Level 4 Practitioner (psychologist or psychiatrist)?**

Not applicable (not attended the training)

Never

Monthly

Every 6 weeks

Every 2 months

Other (please specify).....

**7. The following statements relate to how confident you feel at identifying and responding to psychological distress. Please circle a number to indicate your level of agreement with each statement.**

**a)** *I am confident in my ability to recognise when a patient/carer is experiencing psychological distress.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

**b)** *I am confident in my ability to provide supportive listening when a patient/carer expresses psychological distress.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

**c)** *I am confident in my ability to communicate information to patients/carers in a sensitive manner.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

**d)** *I am confident in my ability to conduct assessments to screen patients/carers for psychological distress.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

Approximately how often do you perform this task?

Daily

Several times per week

Weekly

1-2 times per month

Never

Other (please specify).....

*e) I am confident at using psychological techniques to support patients/carers who are experiencing distress (e.g. problem-solving).*

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

Approximately how often do you perform this task?

Daily

Several times per week

Weekly

1-2 times per month

Never

Other (please specify).....

*f) I am confident at recognising when a patient/carer requires referral for more specialist psychological support or intervention.*

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

### Hospice Facilities

**8. In what setting(s) do you provide psychological support to Hospice patients/carers?**

**Tick all that apply.**

Not applicable

At the Hospice

At patient/carer's home

Over the telephone

Other (please specify).....

**9. Please rate the current facilities at the Hospice in each of the following areas:**

*a) Availability of quiet spaces to talk to patients/carers who are distressed.*

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

Not aware

**b) Availability of information and resources to give to patients/carers about psychological support that they can access.**

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

Not aware

**c) Availability of appropriate levels of psychological support to refer/signpost to.**

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

Not aware

**10. How conducive do you feel the overall environment at the Hospice is to providing psychological support? Please add any comments below.**

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

.....

.....

.....

**11. Are there any factors that you feel act as barriers to you being able to provide support to patients/carers experiencing psychological distress?**

.....

.....

.....

**12. Are there any other facilities or resources that you think would improve the psychological support available for patients/carers?**

.....

.....

.....

## Section B

Throughout this section, please give your answers in relation to the service currently being provided by the Clinical Psychologist working at the XXX Hospice.

### 1. Referrals

**a. Have you made, or prompted, any referrals to the Clinical Psychologist?**

Yes - Please complete the rest of Questions 1 and 2

No - Please skip to Question 3: Consultation (p9)

**b. Approximately how many referrals have you made to the Clinical Psychologist during the past 3 months?**

.....

**c. Do you refer all patients/carers who you think might require Level 3 or Level 4 psychological support?**

Yes

No - Please give details of the reasons why not below (e.g. waiting times, availability, accessibility, patient declined, patient already receiving psychological support from another professional )

.....

.....

.....

**d. What concerns do you most frequently refer patients/carers to the Clinical Psychologist for? Please rank the items that apply, rating the most frequent as '1' and the next most frequent as '2', and so on.**

Existential concerns (e.g. loss of meaning, coping with feelings around death)

Depression

Anxiety

Anger/aggression

Physical problems (e.g. pain)

Cognitive problems (e.g. confusion, memory)

Family/carer issues.

Bereavement

Other (please specify).....

**e. Do you feel that the process for making referrals to the Clinical Psychologist is clear?**

1	2	3	4	5
Not at all	Slightly	Moderately	Very	Extremely

**f. Do you have any suggestions for improving the referrals process?**

.....

.....

.....

## **2. Feedback**

**a. How satisfied are you with any written feedback received from the Clinical Psychologist following a referral?**

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

Not applicable

**b. How satisfied are you with any verbal feedback received from the Clinical Psychologist following a referral?**

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

Not applicable

**c. Do you have any suggestions for improving the feedback?**

.....

.....

.....

## **3. Consultation**

**a. Have you ever sought consultation from the Clinical Psychologist (asked for their professional opinion or advice regarding a patient or carer)?**

Yes - *Please complete the rest of Question 3*

No - *Please skip to Question 4: Supervision with the Clinical Psychologist (p9, below)*

**b. Approximately how often do you seek consultation from the Clinical Psychologist?**

Once per week

Twice per month

Once per month

Less than once per month (please specify).....

**c. How satisfied are you with the input you receive during consultations with the Clinical Psychologist?**

1	2	3	4	5
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

Not applicable

**d. Do you have any suggestions for improving the consultation process?**

.....

.....

.....

#### 4. Supervision with the Clinical Psychologist

**a. Do you attend supervision with the Clinical Psychologist?**

Yes - *Please complete the rest of Question 4*

No - *Please skip to Question 5: Training (p10)*

**b. Please tick to indicate the type of supervision, and frequency with which you attend.**

Group: Family Support Team	Group: Level 2 Psychological Skills	Individual
Monthly Every 6 weeks Every 2 months Less (please specify) .....	Monthly Every 6 weeks Every 2 months Less (please specify) .....	Monthly Every 6 weeks Every 2 months Less (please specify) .....

**c. Are there any barriers to being able to attend supervision sessions with the Clinical Psychologist? Please give details below.**

.....

.....

.....

**d. How satisfied are you with the supervision you have received from the Clinical Psychologist?**

1	2	3	4	5
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

**e. Do you have any suggestions for improving the supervision provided by the Clinical Psychologist?**



.....

.....

.....

## 5. Training

- a. Have you attended any of the following in-service training sessions delivered by Clinical Psychologists at the Hospice since 2009? Please tick all that apply.**

Distress thermometer  
 Family Work from a Psychological Perspective  
 Hallucinations and Paranoia  
 Clinical Psychology with Hospice IPU Settings.  
 Making Connections with Patients  
 Recognising and Responding to Emotional Distress  
 The Personal and Professional Impact of Working in Palliative Care  
 Recognising and Responding to Emotional Distress in Palliative Care Patients  
 None of the above

- b. How satisfied are you with the quality of the in-service psychology training you have received?**

1	2	3	4	5
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

Not applicable

- c. How satisfied are you with the availability of in-service psychology training?**

1	2	3	4	5
Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied

- d. Do you have any suggestions for improving the provision of in-service psychology training?**

.....

.....

.....

- e. Do you have any suggestions for future training sessions related to psychological support that you would like to attend if they were available?**

.....

.....

.....

## 6. General

### a. How would you rate the general approachability of the Clinical Psychology service?

Please add any additional comments below.

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

Comments.....

.....

.....

### b. How would you rate the general availability of the Clinical Psychology service?

Please add any additional comments below.

1	2	3	4	5
Very poor	Poor	Neutral	Good	Very good

Comments.....

.....

.....

### c. To what extent do you feel that the Clinical Psychologist is an integrated member of the multidisciplinary team at the Hospice?

Please add any additional comments below.

1	2	3	4	5
Not at all	Slightly	Moderately	Very much	Extremely

Comments.....

.....

.....

- d. How important do you feel each of the following roles of the Clinical Psychologist are to the Hospice?

**Consultation with staff:**

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

**Supervision:**

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

**Training:**

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

**Direct clinical work with patients/carers:**

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

- e. How would you rate the current amount of Clinical Psychology service provision in each of the following areas?

**Consultation with staff:**

1	2	3
Not enough	About right	Too much

**Supervision:**

1	2	3
Not enough	About right	Too much

**Training:**

<b>1</b>	<b>2</b>	<b>3</b>
Not enough	About right	Too much

**Direct clinical work with patients/carers:**

<b>1</b>	<b>2</b>	<b>3</b>
Not enough	About right	Too much

- f. Do you have any other comments you would like to make about the Clinical Psychology service?**

.....

.....

.....

.....

.....

.....

**Thank you for your time in completing this questionnaire.**

Please return your completed questionnaire to Flora Wilson in the envelope provided, with a signed copy of the consent form.

## Appendix C: Beliefs about Fatigue Scale- Main Research Project

Please indicate to what extent you personally agree or disagree with each statement by circling a number on the scale.

<b>1. My fatigue can be caused by over-activity:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>2. It is important to avoid exercise when I feel tired:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>3. I believe that my fatigue is caused by a virus or infection:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>4. Doing less activity than usual helps to improve my fatigue:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>5. My fatigue can be caused by failing to get enough rest:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>6. Doing exercise is harmful to me:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>7. My fatigue can be caused by stress:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>8. I am worried that I may lose control over my fatigue:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>9. When I do a lot of activity in one day, I know it will worsen my fatigue for the rest of the week:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>10. I have little ability to manage my fatigue:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

<b>11. I feel my fatigue is ruining my ability to enjoy life:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>12. I can't predict how bad my fatigue will be from one day to the next:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>13. When I feel irritable, depressed or anxious, it is mostly because of my fatigue:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>14. My fatigue prevents me from doing what I want:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree
<b>15. I avoid or cancel plans when my fatigue is bad:</b>											
Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

## Appendix D: Instructions to authors for *Aging and Mental Health*

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### 1. General guidelines

- Manuscripts are accepted only in English. Any consistent spelling and punctuation styles may be used. Please use single quotation marks, except where ‘a quotation is “within” a quotation’. Long quotations of 40 words or more should be indented without quotation marks.
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- Section headings should be concise. The text should normally be divided into sections with the headings Introduction, Methods, Results, and Discussion. Long articles may need subheadings within some sections to clarify their content.
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- Description of the Journal's reference style.
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- Figures must be saved separate to text. Please do not embed figures in the manuscript file.
- Files should be saved as one of the following formats: TIFF (tagged image file format), PostScript or EPS (encapsulated PostScript), and should contain all the necessary font information and the source file of the application (e.g. CorelDraw/Mac, CorelDraw/PC).
- All figures must be numbered in the order in which they appear in the manuscript (e.g. Figure 1, Figure 2). In multi-part figures, each part should be labelled (e.g. Figure 1(a), Figure 1(b)).
- Figure captions must be saved separately, as part of the file containing the complete text of the manuscript, and numbered correspondingly. The captions should include keys to symbols, and should make interpretation possible without reference to the text.
- The filename for a graphic should be descriptive of the graphic, e.g. Figure1, Figure2a.

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- Information about supplemental online material
- 

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## **Appendix E: Instructions to authors for *Palliative Medicine***

**SAGE**

### **Manuscript Submission Guidelines: Palliative Medicine**

*Palliative Medicine* is a highly ranked, peer reviewed scholarly journal dedicated to improving knowledge and clinical practice in the palliative care of patients with far advanced disease. It reflects the multi-disciplinary and multi-professional approach that is the hallmark of effective palliative care. Papers are selected for publication based on their scientific excellence, contribution to knowledge, and their importance to contemporary palliative care. We welcome papers relating to palliative care clinical practice, policy, theory and methodological knowledge.

*Palliative Medicine* is an international journal, and is the official research journal of the European Association for Palliative Care and a journal of the Association of Palliative Medicine. Whilst we acknowledge that many papers will focus on palliative care issues within particular countries, it is important to our readers that authors reflect on how these issues might be relevant to a wider audience, present the study in the context of the existing international research on the topic, and discuss how this knowledge contributes to the international knowledge base.

#### **1. Peer review policy**

*Palliative Medicine* operates a conventional single blind reviewing policy in which the reviewer's name is always concealed from the submitting authors. All submitted manuscripts undergo a two stage review process. The initial review is undertaken by three editors and a decision is made either to send the paper for external review or to reject it without review. We undertake to make the decision whether or not to send for external review within three weeks of submission. In this initial review the editors ensure that only those papers that meet the scientific and editorial standards of the journal and fit within the aims and scope of the journal will be sent for external review. Within 10 weeks of sending the paper out to external review we will make a final decision. Papers accepted for publication following external review usually require some modification before final acceptance. Generally, due to the high volume of submissions, we are able to accept only about 30% of papers submitted to us.

#### **2. Article types**

*Palliative Medicine* publishes original research and review articles on all aspects of palliative care. The Journal considers the following kinds of article for publication:

1. Review Articles – 5,000 words. The reviews we publish are usually systematically constructed reviews, clearly following the relevant publication guidelines (such as PRISMA) for the particular review style chosen. We are happy to consider a range of review types (systematic reviews, meta- analysis, meta-ethnography, realist review for example) for publication, but they must be methodologically clear and rigorously conducted.
2. Original Articles – 3,000 words with up to six tables or figures. For papers reporting qualitative methods participants' quotations may be excluded from the word count. We

still prefer, however, that these quotations are succinct and carefully chosen – it is rare that more than one quote is required to illustrate the point being made. All research papers should follow relevant reporting guidelines such as CONSORT for trials, COREQ for qualitative research etc. Please see <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/> for up to date information on reporting guidelines, and fuller instructions below on constructing different aspects of the paper.

3. Short reports – 1,000-1,400 words. These should report research, but are usually small scale survey/pilot/feasibility studies etc, which would not warrant a full original research paper

4. Case reports – 1,000-1,400 words with one table or figure. We have specific and explicit requirements for case report abstracts and the construction of the report (see below) which must be followed. Case reports must be used to generate future research questions.

5. Audit and Service Evaluation. 1 000- 1,400 words. We do accept audit and service evaluation reports, but these should be of exceptional quality and interest. These should be robustly reported – we expect audits to discuss the audit cycle and feedback, and service evaluations to report sufficient contextual information on the service being evaluated. They should be used to raise future research questions. Full details of all relevant permissions and consents should be reported.

6. Research letters. We occasionally publish short research letters (750 words, no abstract required, no more than 3 references). These are usually offered as a publication type to authors submitting original papers or short reports which we feel should be disseminated, but in a more succinct form.

7. Letters to the editors. We welcome correspondence relating to issues of general interest to our readership, or in response to a publication. Such letters should be succinct, and generally no more than 500 – 750 words.

NB: word count excludes references, tables and figures references

## **2.1 Structured abstracts**

Reviews, original articles, short reports, case reports, audits and service evaluations should be accompanied by a structured abstract. Full details are given below of the format we expect for these:

### **Research Paper/Short Report/Audit/Service Evaluation:**

Abstracts should have clear headings, which should generally follow the structure below when reporting research, but may vary depending on the requirements of the reporting guidelines followed. There is some flexibility for audit/service evaluation as it is important that these are not presented as research.

**Background:** Identify the issue to be addressed, current knowledge on the topic and some indication of its relevance and importance to clinical practice, theory or research methodology.

**Aim:** A clear statement of the main research aim(s), research question (s) or hypotheses to be tested.

**Design:** A statement about the research strategy adopted. For intervention studies, a clear statement of the intervention is required. For clinical trials, the trial number should be given.

**Setting/participants:** Indicate the type of setting(s) the research was conducted in (i.e. primary/secondary care), the number of centres, and who participated including brief indication of inclusion/exclusion criteria, numbers of participants and any relevant characteristics.

**Results:** Report the main outcomes(s) findings of the study. If appropriate, report levels of statistical significance and confidence intervals.

**Conclusions:** Identify how the aims have been met, and the relevance of the findings for clinical practice, theory or research methodology. Suggestions for further research.

### **Review Paper**

These should generally follow the structure below, with reference to relevant review reporting guidelines such as PRISMA.

**Background:** Identify the issue to be addressed, current knowledge on the topic and some indication of its relevance and importance to clinical practice, theory or research methodology.

**Aim:** A clear statement of the review aim(s).

**Design:** A statement about the review strategy/methods adopted

**Data sources:** State the data sources used (including years searched). Include a statement about eligibility criteria for selecting studies and study quality appraisal

**Results:** Report the main outcomes(s) /findings of the review.

**Conclusions:** Identify how the aims have been met, and the relevance of the findings for clinical practice, theory or research methodology.

### **Case Report**

This format differs from our structured abstracts for research or reviews, so please ensure you follow the correct format or your paper will be returned without review. Case report abstracts should be 200 words in length.

**Background:** Identify the issue the case report addresses, why this case is important, current knowledge on the topic, and some indication of the case relevance to practice and research.

**Case Presentation:** Presenting features of the case(s) and working/differential diagnoses. Brief summary of case(s) history, examinations and investigations etc.

**Case Management:** Details of any treatment given and a description of the course of the clinical issue(s) being reported.

**Case Outcome:** Description of case(s) outcome. Details of any outcome measures used.

**Conclusions:** Identify how the aims have been met, and the relevance of the findings for clinical practice, theory or research methodology. Suggestions for further research.

## **2.2 General instructions to authors relevant to all paper types**

We wish papers published by *Palliative Medicine* to adhere to the highest publishing standards possible. We want to ensure that the key messages for our readers are explicitly articulated. We also want you to consider the following issues: authorship; multiple publications; ethical approvals; research design; and presentation of discussion.

### **Key Statements**

Palliative Medicine has a system where all papers are required to clearly state what is already known about the topic, what their paper adds, and implications for practice, theory, or policy. You are required to give these at the start of the manuscript. Please use these three specific headings (see below), with 1-3 separate bullet points for each heading. Please use clear, succinct, separate bullet points rather than complex or multiple sentences. Each bullet point should be one sentence only.

### **What is already known about the topic?**

- Short statement(s) here about state of knowledge in this area.
- You may highlight both what is known and what is not known.
- Be specific rather than broad or sweeping statements. Avoid statements such as 'Little is known about ... x or y' in favour of statements specifying exactly what is known.

### **What this paper adds?**

- Short specific statement(s) here about what this paper adds.
- These should be styled in terms of outcomes where possible (This study demonstrates that x intervention has a (specific) impact on y outcome) rather than study aims or process. (This study considers whether x intervention has an impact of y outcome).
- Be as specific as possible please here. Avoid broad statements such as 'New Knowledge is added about ... ' but rather be specific about exactly what this knowledge is. So for example rather than 'We add to the knowledge base on x' we would prefer the specific such as 'x variable was found to increase the experience of y outcome (by z amount)'.- Ensure that these statements clearly relate to the findings of the study.

### **Implications for practice, theory or policy?**

- Short specific statement(s) here on the implications of this paper for practice, theory or policy. These should clearly draw from the findings of the study, without over stating their importance.
- Where possible please make these internationally relevant.

### *Authorship:*

*Palliative Medicine* adheres to the guidelines from the International Committee of Medical Journal Editors in ascribing authorship. These state that authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. A statement regarding authorship should be included in your covering letter to the editor. Full details of the ICMJE regarding authorship can be found here [http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html).

### *Multiple publications:*

We want our readers to be aware of other published or in-press accounts of any studies published in *Palliative Medicine*. For this reason we ask that all published and in-press accounts of the study from which data in your paper are taken must be explicitly

referred to in your paper. Please make it clear in your manuscript that you are referring to data/publications from the same study. If you have other publications from the same study in preparation or under review please refer to this in your letter to the editor. If you are successful in your submission to *Palliative Medicine* we ask that where possible this publication should be referred to in other manuscripts using data from the same study.

#### *Ethical issues:*

We expect all studies that we publish to be conducted to high ethical standards which adhere to local ethical regulations and standards. We recommend that studies follow the recommendations of the International Committee of Medical Journal Editors.

[http://www.icmje.org/ethical\\_6protection.html](http://www.icmje.org/ethical_6protection.html).

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

Manuscripts reporting research studies must state at an appropriate point how such local regulations and standards have been met. Where applicable the approving body and approval number should be given.

#### *Research design/reporting issues*

Research reports frequently omit important information. *Palliative Medicine* recommends that authors use, where possible, reporting guidelines to assist them in providing all the relevant information required by our readers. Reporting guidelines are statements that provide advice on how to report research methods and findings. Usually in the form of a checklist, flow diagram or explicit text, they specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular issues that might introduce bias into the research. Most widely recognised guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field, including research methodologists and journal editors.

*Palliative Medicine* asks that guidelines are followed relevant to the research design used. Not being able to meet all of the requirements of a guideline is not necessarily a barrier to publishing your manuscript, but all essential requirements of the research design should be met. You can, if you wish, submit a checklist with your manuscript as a guide to the editors and reviewers of the paper. The Equator Network is a useful resource, with links to many widely used guidelines: <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/>

Examples of guidelines the editors would expect to be used include:

The CONSORT guidelines for Randomised Controlled Trials (<http://www.consort-statement.org>). In addition *Palliative Medicine* has adopted the proposal from the International Committee of Medical Journal Editors (ICMJE) which requires, as a



condition of consideration for publication of clinical trials, registration in a public trials registry. Trials must register at or before the onset of patient enrolment. The clinical trial registration number should be included at the end of the abstract of the article. For this purpose, a clinical trial is defined as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g. phase I trials), would be exempt. Further information can be found at [www.icmje.org](http://www.icmje.org).

The STARD guidelines for studies of diagnostic accuracy <http://www.stard-statement.org>

The PRISMA or MOOSE guidelines for systematic reviews and meta-analyses <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/systematic-reviews-and-meta-analysis/>

The STROBE guidelines for observational studies in epidemiology <http://www.strobe-statement.org>

The COREQ guidelines for reporting qualitative research <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/qualitative-research/>

## **Study discussion**

Although Palliative Medicine does not require structured discussions, we would like you to bear in mind the typical content for a structured discussion when writing your paper. This would typically be a statement of the principal findings of the study, a discussion of the strengths and weaknesses of the study/review with reference to other studies or reviews in the area, a discussion of what is already known about this topic and what this research/review adds, and a discussion of the implications of the research/review for clinical practice, theory or methods in this area. You may wish to raise further research or review questions.

## **2.3 Case report instructions for Palliative Medicine**

The purpose of our case reports: We are interested in publishing unusual clinical presentations or novel approaches to care. As a research focused journal, we publish case reports to highlight issues of clinical interest which help readers to pose research questions for future further study, and so we want these research focused learning points to be explicit within the report.

Case report length: Case reports should be succinct and focused. They should be between 1000 and 1400 words in length. The aim is description of the case, without undue speculation.

Case report instructions: Case report authors should also read our general instructions to authors regarding title, keywords, article retrievability, authorship and other general formatting issues. Case reports should include the words ‘case report’ or ‘case series’ as appropriate in the title and keywords. Please do not use ‘case study’ as this leads to confusion with the research strategy of the same name.

**2.3.1 Case report format:** The format for the written case report should, where possible, follow the same structured format as for the abstract, but in greater detail.

**Background:** Identify the issue the case report addresses, why this case is important, current knowledge on the topic, and some indication of the case relevance to practice and research. The case should be placed in context, remembering that *Palliative Medicine* is an international journal and readers are unlikely to be familiar with the particular context in which this case(s) occurred. You should briefly make reference to any similar published cases, and related research findings.

**Case presentation:** Presenting features of the case(s) and working/differential diagnoses. Brief summary of case(s) history, examinations and investigations etc. Cases presented in *Palliative Medicine* should be anonymised. Sufficient detail should be given so that the case is informative to the reader, but the patient should not be able to be identified from the case information. Details should be given in this section or in a final 'consent' section of the permissions the patient(s) gave for their case(s) to be written for publication. Where possible patients should sign an informed consent form which is submitted as a supplementary file to the case report, and this should be noted in the report. We do expect written informed consent for most of the case reports we publish, however we acknowledge that this can be challenging in the field of palliative care with potentially rapidly deteriorating patients. If the patient has died, as a next step we would expect the authors to request permission from a relative, and make this clear on the consent form and in the report. If no written consent is possible from either patient or relative we will carefully consider the utility of the case against the likelihood of identification or potential distress. To reduce the possibility of identification then it is likely that in this position more information will have to be removed from the case, and this will have to be made clear in the report.

**Case management:** Details of any treatment given and a description of the course of the clinical issue(s) being reported. Drug names should be generic not proprietary. Details of management should be specific and described to be understandable by those who may follow different protocols in different contexts. A rationale should be given for any changes in management. An indication of timescale should be included. Case outcome: Description of case(s) outcome. Details of any outcome measures used.

**Conclusions:** Indication of novelty of this case(s) with reference to other published cases and any existing research. Description of lessons learnt from the case(s) and implications for future research. It is particularly important that these learning points from the case are clearly spelt out. In particular, as a research journal, we expect a clear statement of the research questions or areas that could be investigated that follow from this case(s).

Case reports should usually have no more than 8 references and include no more than 1 table or figures.

### **3. How to submit your manuscript**

Before submitting your manuscript, please ensure you carefully read and adhere to all the guidelines and instructions to authors provided below. Manuscripts not conforming to these guidelines may be returned.

*Palliative Medicine* is hosted on SAGE track - a web based online submission and peer review system powered by ScholarOne Manuscripts. Please read the Manuscript

Submission guidelines below, and then simply visit <http://mc.manuscriptcentral.com/palliative-medicine> to login and submit your article online.

**IMPORTANT:** Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne

All papers must be submitted via the online system. If you would like to discuss your paper prior to submission, please contact the journal by e-mail to Debbie Ashby [[Debbie.Ashby@bristol.ac.uk](mailto:Debbie.Ashby@bristol.ac.uk)].

#### **4. Journal contributor's publishing agreement**

Before publication SAGE requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. SAGE's Journal Contributor's Publishing Agreement is a exclusive licence agreement which means that the author retains copyright in the work but grants SAGE the sole and exclusive right and licence to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than SAGE. In this case copyright in the work will be assigned from the author to the society. For more information please visit our [Frequently Asked Questions](#) on the SAGE Journal Author Gateway.

##### **4.1 SAGE Choice**

If you wish your article to be freely available online immediately upon publication (as some funding bodies now require), you can opt for it to be included in SAGE Choice subject to payment of a publication fee. The manuscript submission and peer reviewing procedure is unchanged. On acceptance of your article, you will be asked to let SAGE know directly if you are choosing SAGE Choice. For further information, please visit [SAGE Choice](#).

#### **5. Declaration of conflicting interests**

Within your Journal Contributor's Publishing Agreement you will be required to make a certification with respect to a declaration of conflicting interests. It is the policy of *Palliative Medicine* to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please include any declaration at the end of your manuscript after any acknowledgements and prior to the references, under a heading 'Conflict of Interest Statement'. If no declaration is made the following will be printed under this heading in your article: 'None Declared'. Alternatively, you may wish to state that 'The Author(s) declare(s) that there is no conflict of interest'.

When making a declaration the disclosure information must be specific and include any financial relationship that all authors of the article has with any sponsoring organization

and the for-profit interests the organization represents, and with any for-profit product discussed or implied in the text of the article.

Any commercial or financial involvements that might represent an appearance of a conflict of interest need to be additionally disclosed in the covering letter accompanying your article to assist the Editor in evaluating whether sufficient disclosure has been made within the Conflict of Interest statement provided in the article.

For more information please visit the [SAGE Journal Author Gateway](#).

## **6. Other conventions**

None.

## **7. Acknowledgements**

Any acknowledgements should appear first at the end of your article prior to your Declaration of Conflicting Interests (if applicable), any notes and your References.

All contributors who do not meet the criteria for authorship should be listed in an 'Acknowledgements' section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Authors should disclose whether they had any writing assistance and identify the entity that paid for this assistance.

### **7.1 Funding Acknowledgement**

To compile with the guidance for Research Funders, Authors and Publishers issued by the Research Information Network (RIN), *Palliative Medicine* additionally requires all Authors to acknowledge their funding in a consistent fashion under a separate heading. All research articles should have a funding acknowledgement in the form of a sentence as follows, with the funding agency written out in full, followed by the grant number in square brackets:

This work was supported by the Medical Research Council [grant number xxx].

Multiple grant numbers should be separated by comma and space. Where the research was supported by more than one agency, the different agencies should be separated by semi-colon, with and before the final funder. Thus:

This work was supported by the Wellcome Trust [grant numbers xxxx, yyyy]; the Natural Environment Research Council [grant number zzzz]; and the Economic and Social Research Council [grant number aaaa].

In some cases, research is not funded by a specific project grant, but rather from the block grant and other resources available to a university, college or other research institution. Where no specific funding has been provided for the research we ask that corresponding authors use the following sentence:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Please include this information under a separate heading entitled 'Funding' directly after any other Acknowledgements prior to your 'Declaration of Conflicting Interests' (if applicable), any Notes and your References. For more information on the guidance for Research Funders, Authors and Publishers, please visit: <http://www.rin.ac.uk/funders-acknowledgement>

## **8. Permissions**

Authors are responsible for obtaining permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please visit our [Frequently Asked Questions](#) on the SAGE Journal Author Gateway..

## **9. Manuscript style**

### **9.1 File types**

Only electronic files conforming to the journal's guidelines will be accepted. Preferred formats for the text and tables of your manuscript are Word DOC, RTF, XLS. LaTeX files are also accepted. Please also refer to additional guideline on submitting artwork below.

### **9.2 Journal Style**

*Palliative Medicine* conforms to the SAGE house style. [Click here](#) to review guidelines on SAGE UK House Style.

### **9.3 Reference Style**

*Palliative Medicine* operates a SAGE Vancouver reference style. [Click here](#) to review the guidelines on SAGE Vancouver to ensure your manuscript conforms to this reference style

### **9.4. Manuscript Preparation**

The text should be double-spaced throughout and with a minimum of 3cm for left and right hand margins and 5cm at head and foot. Text should be standard 10 or 12 point.

#### **9.4.1 Your Title, Keywords and Abstracts: Helping readers find your article online**

The title, keywords and abstract are key to ensuring readers find your article online through online search engines such as Google. Please refer to the information and guidance on how best to title your article, write your abstract and select your keywords by visiting SAGE's Journal Author Gateway Guidelines on [How to Help Readers Find Your Article Online](#).

*Palliative Medicine* requires authors to list between 4 and 6 key words that are also Medical Subject Headings (MESH headings). These key words should be closely related to the papers subject, purpose, method and focus. Details of MESH headings can

be found here <http://www.nlm.nih.gov/mesh/>. If authors submit keywords that are not MESH headings *Palliative Medicine* reserves the right to submit alternative keywords.

Abstracts for *Palliative Medicine* should be structured and no more than 250 words. They should not include references or abbreviations. Please refer to section 2 above.

#### **9.4.2 Corresponding Author Contact details**

Provide full contact details for the corresponding author including email, mailing address and telephone numbers. Academic affiliations are required for all co-authors. These details should be presented separately to the main text of the article to facilitate anonymous peer review.

#### **9.4.3 Guidelines for submitting artwork, figures and other graphics**

For guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit SAGE's [Manuscript Submission Guidelines](#).

Figures supplied in colour will appear in colour online regardless of whether or not these illustrations are reproduced in colour in the printed version. For specifically requested colour reproduction in print, you will receive information regarding the costs from SAGE after receipt of your accepted article.

#### **9.4.4 Guidelines for submitting supplemental files**

This journal is able to host approved supplemental materials online, alongside the full-text of articles. Supplemental files will be subjected to peer-review alongside the article. For more information please refer to SAGE's [Guidelines for Authors on Supplemental Files](#).

#### **9.4.5 English Language Editing services**

Non-English speaking authors who would like to refine their use of language in their manuscripts might consider using a professional editing service. Visit <http://www.uk.sagepub.com/journalgateway/msg.htm> for further information.

### **10. After acceptance**

#### **10.1 Proofs**

We will email a PDF of the proofs to the corresponding author. Any corrections should be sent to the editors within two weeks of receipt.

#### **10.2 E-Prints**

SAGE provides authors with access to a PDF of their final article. For further information please visit [Offprints](#) and [Reprints](#) on our Journal Author Gateway.

#### **10.3 SAGE Production**

At SAGE we place an extremely strong emphasis on the highest production standards possible. We attach high importance to our quality service levels in copy-editing, typesetting, printing, and online publication (<http://online.sagepub.com/>). We also seek to uphold excellent author relations throughout the publication process.

We value your feedback to ensure we continue to improve our author service levels. On publication all corresponding authors will receive a brief survey questionnaire on your experience of publishing in *Palliative Medicine* with SAGE.

#### **10.4 OnlineFirst Publication**

*Palliative Medicine* benefits from OnlineFirst, a feature offered through SAGE's electronic journal platform, SAGE Journals Online. It allows final revision articles (completed articles in queue for assignment to an upcoming issue) to be hosted online prior to their inclusion in a final print and online journal issue which significantly reduces the lead time between submission and publication. For more information please visit our [OnlineFirst Fact Sheet](#)

#### **11. Further information**

Any correspondence, queries or additional requests for information on the Manuscript Submission process should be sent to the Editorial Office as follows:

Debbie Ashby  
Editorial Manager  
[debbie.ashby@bristol.ac.uk](mailto:debbie.ashby@bristol.ac.uk)

## Appendix F: Instructions to authors for *Journal of Psychosomatic Research*



### JOURNAL OF PSYCHOSOMATIC RESEARCH

Official Journal of the [European Association of Psychosomatic Medicine](#) and affiliated with the [International College of Psychosomatic Medicine](#)

#### AUTHOR INFORMATION PACK

### Your Paper Your Way

We now differentiate between the requirements for new and revised submissions. You may choose to submit your manuscript as a single Word or PDF file to be used in the refereeing process. Only when your paper is at the revision stage, will you be requested to put your paper in to a 'correct format' for acceptance and provide the items required for the publication of your article.

**To find out more, please visit the Preparation section below.**



#### Introduction

### Types of article

#### Full Length Papers

Full length research papers will not normally be more than 4000 words in length (Introduction through Discussion) and will preferably be shorter. Submission of a paper to the Journal of Psychosomatic Research will be held to imply that it represents original research not previously published (except in the form of an abstract or preliminary report), that it is not being considered for publication elsewhere, and that if accepted by the Journal of Psychosomatic Research it will not be published elsewhere in the same form in any language without the consent of the Publisher. Major papers of topical content will be given priority in publication. **Please note that this journal does not publish animal studies.**

#### Short Reports

The journal welcomes short reports, which may be either preliminary communications or brief accounts of original research. Short Reports must not exceed 1500 words and should include no more than 2 tables and 30 references. The journal does not publish case reports.

#### Editorials

The Editors welcome suggestions for editorials which give personal and topical views on subjects within the journal's area of interest. They should not normally exceed 1500 words, excluding references and should have no more than 20 references.

#### Review Articles

Review papers are normally 4000-5000 words (Introduction through Discussion).



Authors are advised to consult one of the Editors with an outline before submitting a review.

### **Letters to the Editors**

These normally refer to articles previously published in the journal. The Editors are also willing to consider letters on subjects of direct relevance to the journal's interest, including research letters. Letters should not exceed 1000 words, including references. Where appropriate, they should begin with a reference to the published article that is the subject of the letter. Research letters should be submitted as 'Letters to the Editors'

### **Book Reviews**

These are normally submitted by the Book Review Editor. In addition we welcome suggestions of books for review.

### **Special Articles**

These may be invited by an editor or submitted after discussion with an editor. Special articles are designed to provide an analysis of a topic of particular interest to readers of the journal and are more extensive in scope than an editorial. They should not primarily be a commentary on an article previously published in the journal, which would be better addressed in a letter or editorial.

### **Other Papers**

The Editors welcome suggestions for other types of papers, such as conference reports, accounts of major research in progress and interviews with senior research workers. These should not be submitted without prior consultation with an editor.

### **European Association for Consultation-Liaison Psychiatry and Psychosomatics (EALCPP) Contributions**

These should not exceed 1000 words, excluding references. Contributions are not meant to publish results of specific disease-related research; topics covered should be of general interest, stem from countries participating in the EACLPP or refer to EACLPP activities. EACLPP contributors are not peer-reviewed but subject to editorial approval. In case of doubt about the suitability of a subject, please contact [jpsychores@elsevier.com](mailto:jpsychores@elsevier.com)

### **Contact details for submission**

Journal of Psychosomatic Research  
Editorial Office  
E-mail: [jpsychores@elsevier.com](mailto:jpsychores@elsevier.com)



**Before You Begin**

### **Ethics in publishing**

For information on Ethics in publishing and Ethical guidelines for journal publication see <http://www.elsevier.com/publishingethics> and <http://www.elsevier.com/journal-authors/ethics>.

### **Human and animal rights**

If the work involves the use of animal or human subjects, the author should ensure that

the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans <http://www.wma.net/en/30publications/10policies/b3/index.html>; EU Directive 2010/63/EU for animal experiments [http://ec.europa.eu/environment/chemicals/lab\\_animals/legislation\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm); Uniform Requirements for manuscripts submitted to Biomedical journals <http://www.icmje.org>. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

### **Conflict of interest**

All authors are requested to disclose any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work. See also <http://www.elsevier.com/conflictsofinterest>. Further information and an example of a Conflict of Interest form can be found at: [http://help.elsevier.com/app/answers/detail/a\\_id/286/p/7923](http://help.elsevier.com/app/answers/detail/a_id/286/p/7923).

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## **Appendix G: Department of Psychology Ethical Approval for SIP Questionnaire (13-129) and Focus Group/Interviews (14-015)**

Date: Wed, 03 Jul 2013 16:30:09 +0100  
From: Jeffrey Gavin <J.Gavin@bath.ac.uk>  
To: Flora Wilson <F.C.L.Wilson@bath.ac.uk>, Caroline Ransford <C.A.Ransford@bath.ac.uk>  
Subject: ethics ref 13-129

Dear Flora Wilson

Reference Number 13-129

The ethics committee have considered your application for the study entitled 'An evaluation of psychological service provision at the [X] Hospice' and have given it conditional ethical approval.

The committee have raised the following points which they would like you to attend to before giving the study full ethical approval:

- The survey that is included is identified as a draft, and it is stated that it will be developed further. However, it is not clear when or how this will be done and what the final version will be. We need to see this prior to it being sent to participants.
- There is no interview schedule included. This needs to be looked at before approval is given. It is also not clear what the follow up interview will add to the overall study questions or the information gained from the questionnaire.

Please send the revised document to Caroline Ransford - you can do this by email.

Please remember that you may not collect any data until you have ethical approval.

Yours sincerely

Dr Jeff Gavin  
Acting Chair of Psychology Ethics Committee

-----

Dr Jeff Gavin  
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<http://staff.bath.ac.uk/pssjg/index.html>

Date: Wed, 04 Sep 2013 16:40:49 +0100  
From: Psychology-Ethics <psychology-ethics@bath.ac.uk>  
To: fclw20@bath.ac.uk, Caroline Ransford <C.A.Ransford@bath.ac.uk>  
Subject: Ethics 13-129

Dear Flora,

Reference Number 13-129

Thank you for satisfactorily attending to the amendments. I can now confirm that you have full ethical approval for your study.

Best wishes with your research.

--

Dept of Psychology Ethics Committee  
University of Bath

Date: Mon, 10 Feb 2014 14:54:48 +0000  
From: Psychology Ethics Committee <psychology-ethics@bath.ac.uk>  
To: Flora Wilson <F.C.L.Wilson@bath.ac.uk>  
Subject: Ethics 14-015

Dear Flora Wilson


Reference Number 14-015

The ethics committee have considered your ethics proposal for the study entitled 'An evaluation of psychological service provision at the [X] Hospice: part 2' and have given it full ethical approval.

Best wishes with your research.

Dr Helen Lucey  
Chair Psychology Ethics Committee  
University of Bath

## Appendix H: Department of Psychology ethical approval for Main Research Project

<p><b>Dr Andrew Medley</b> Research Tutor &amp; Clinical Psychologist Member of Psychology Ethics Committee Telephone +44 01225 383788 E-mail: A.R.Medley@bath.ac.uk</p>	<p> UNIVERSITY OF <b>BATH</b> <b>Department of Psychology</b> Bath BA2 7AY · United Kingdom</p>
--	---

22<sup>nd</sup> December 2014

Flora Wilson  
Doctorate in Clinical Psychology  
University of Bath

Dear Flora

**Ethics application: 14-250**

**Title of project:** Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome/Myalgic Encephalomyelitis and Insomnia

The Psychology Ethics Committee has considered your ethics proposal for the above study and given it full ethical approval.

Best wishes with your research.

Yours sincerely



Dr Andrew Medley  
Research Tutor & Clinical Psychologist  
Psychology Ethics Committee



## Appendix I: REC approval for Main Research Project



### Health Research Authority

#### NRES Committee East Midlands - Leicester

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Telephone: 0115 8839436

16 December 2014

Miss Flora Wilson  
Department of Psychology  
University of Bath  
Claverton Down, Bath  
BA2 7AY

Dear Miss Wilson

<b>Study title:</b>	<b>Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome/Myalgic Encephalomyelitis and Insomnia</b>
<b>REC reference:</b>	<b>14/EM/1297</b>
<b>Protocol number:</b>	<b>N/A</b>
<b>IRAS project ID:</b>	<b>156785</b>

Thank you for your letter of 11 December 2014, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant Joanne Unsworth, [nrescommittee.eastmidlands-leicester@nhs.net](mailto:nrescommittee.eastmidlands-leicester@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

#### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the

study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

### **Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

### **Approved documents**

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants	2	11 December 2014

[Advert_CFS group v1 06.11.14]		
Copies of advertisement materials for research participants [Advert_Insomnia and Healthy Comparison groups v1 06.11.14]	2	11 December 2014
Copies of advertisement materials for research participants [Website Content_Insomnia and Healthy Comparison groups v1 06.11.14]	2	11 December 2014
Covering letter on headed paper [Covering Letter 24.11.14]	1	24 November 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Bath_Professional Indemnity Insurance_01.08.14]		01 August 2014
IRAS Checklist XML [Checklist_11122014]		11 December 2014
Letter from sponsor [Letter from Sponsor 24.11.14]	1	24 November 2014
Letters of invitation to participant [Letter of Invitation_CFS Group v2 06.11.14]	2	06 November 2014
Non-validated questionnaire [Demographic Information Questionnaire v1 06.11.14]	1	06 November 2014
Non-validated questionnaire [Beliefs about Fatigue Questionnaire v1 06.11.14]	1	06 November 2014
Other [University of Bath_Public Liability_Insurance_01.08.14]		01 August 2014
Other [Summary CV for supervisor_Rachel Hiller_31.10.14]		31 October 2014
Other [Clinician Screening Form v2 06.11.14]	2	06 November 2014
Other [Provisional Opinion Response Letter]	1	11 December 2014
Participant consent form [Consent Form_CFS Group v2 02.11.14]	2	02 November 2014
Participant consent form [Consent Form_Insomnia Group v2 02.11.14]	2	02 November 2014
Participant consent form [Consent Form_Healthy Comparison Group v2 02.11.14]	2	02 November 2014
Participant information sheet (PIS) [Participant Information Sheet_CFS group v2 02.11.14]	3	11 December 2014
Participant information sheet (PIS) [Participant Information Sheet_Insomnia group v2 02.11.14]	3	11 December 2014
Participant information sheet (PIS) [Participant Information Sheet_Healthy Comparison group v2 02.11.14]	3	11 December 2014
REC Application Form [REC_Form_28112014]		28 November 2014
Research protocol or project proposal [Protocol v2 06.11.14]	2	06 November 2014
Summary CV for Chief Investigator (CI) [Summary CV for CI_Flora Wilson_02.11.14]		02 November 2014
Summary CV for supervisor (student research) [Summary CV for supervisor_Prof Paul Salkovskis]		02 November 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Project Summary and Flowchart v1 06.11.14]	1	06 November 2014
Validated questionnaire [Questionnaire Pack v2 06.11.14 (excluding non-validated questionnaires)]	2	06 November 2014

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**14/EM/1297**

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. 

**Mr Ken Willis**  
**Chair**

Email: [nrescommittee.eastmidlands-leicester@nhs.net](mailto:nrescommittee.eastmidlands-leicester@nhs.net)

Enclosures:

Copy to: *Professor Jane Millar*  
*Annette Clarke, North Bristol NHS Trust*

## Health Research Authority

### NRES Committee East Midlands - Leicester

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 883 9436

18 December 2014

Miss Flora Wilson  
Department of Psychology  
University of Bath  
Claverton Down, Bath  
BA2 7AY

Dear Miss Wilson

<b>Study title:</b>	<b>Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome/Myalgic Encephalomyelitis and Insomnia</b>
<b>REC reference:</b>	<b>14/EM/1297</b>
<b>Protocol number:</b>	<b>N/A</b>
<b>Amendment number:</b>	
<b>Amendment date:</b>	<b>18 December 2014</b>
<b>IRAS project ID:</b>	<b>156785</b>

Thank you for your letter of 18 December 2014, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

#### Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Minor Amendment		18 December 2014
Research protocol or project proposal [Protocol - tracked changes]	3	18 December 2014

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for

Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>14/EM/1297:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Ellen Swainston**  
**REC Manager**

E-mail: [nrescommittee.eastmidlands-leicester@nhs.net](mailto:nrescommittee.eastmidlands-leicester@nhs.net)

Copy to: *Annette Clarke, North Bristol NHS Trust*  
*Professor Jane Millar*

## Appendix J: Trust R&D approvals for Main Research Project

### Royal National Hospital for Rheumatic Diseases



NHS Foundation Trust

Upper Borough Walls  
Bath, BA1 1RL  
Telephone: 01225 465941  
Safe Haven fax: 01225 473461

Flora Wilson  
Trainee Clinical Psychologist  
Department of Psychology  
University of Bath  
Bath BA2 7AY

26<sup>th</sup> January 2015

Dear Flora

#### **RBB 446 - Psychological factors in CFS/ME and Insomnia**

Thank you for your application for approval of the above project, which was considered at the R&D Committee meeting on the 20<sup>th</sup> January 2015. I am pleased to inform you that the R&D Committee approved the study subject to the following:-

- Please forward a copy of the final signed SSI to the R&D Office.

The University of Bath will act as sponsor.

Details of this project will be entered onto the RNHRD database. The reference number for your project is **RBB 446** and this should be used in all correspondence. A short progress report will be required annually or at the end of the project, whichever occurs first.

All research approved by the R&D Committee should follow good clinical practice and adhere to the systems in place for Research Governance. All Principal Investigators must undertake Good Clinical Practice training and are responsible for ensuring that their research staff have received appropriate training.

You are responsible for ensuring that, all participants sign informed consent (whenever applicable) and that the protocol agreed by the local research ethics committee is adhered to by yourself and any co-workers.

You are required to provide us with information about any amendments to the protocol, changes in funding, personnel or end date and any research-related adverse events. Any staff working on this study at this site must be issued with a contract with RNHRD (honorary or substantive) or Letter of Access before they commence work on the study at this site. Please make sure that the RNHRD is acknowledged on all academic papers which may be written as a result of this research.

In addition, other information may be requested from time to time and a lay summary of the results will be requested from you at the end of the study. This study may be subject to audit by the R&D Office.

We wish you well with this research.

Yours sincerely

Jane Carter  
R&D Manager



RE: North Bristol NHS Trust Full R&D approval: [Psychological factors in CFS/ME and Insomnia v1], R&I [3414]

Smith Rebecca (NORTH BRISTOL NHS TRUST)

Sent: 13 February 2015 16:06

To: hazel.o'dowd@nbt.nhs.uk

Wilson Flora (TAUNTON AND SOMERSET NHS FOUNDATION TRUST);

Williams Nicola (NORTH BRISTOL NHS TRUST); Helen.Lewis@nbt.nhs.uk;

Cc: stacey.mcgarrahy@nbt.nhs.uk; annette.clarke@nbt.nhs.uk;

Donna.Ghezzi@nbt.nhs.uk; Smith Rebecca (NORTH BRISTOL NHS TRUST);

Mary.kisanga@nbt.nhs.uk; Agnieszka.ziolek@nbt.nhs.uk;

provcresearch@bath.ac.uk

Dear Hazel,

Title: Psychological factors associated with self-reported sleep disturbance in Chronic Fatigue Syndrome/Myalgic Encephalomyelitis and Insomnia

CI: Flora Wilson

IRAS number: 156785

REC number: 14/EM/1297

R&D Reference: 3414

Start Date: 13.02.2015

End Date: 30.09.2015

I am pleased to confirm North Bristol NHS Trust (NBT) NHS permission for the above study.

#### FULL R&D APPROVAL

You have permission to begin recruitment

I understand that the University of Bath will act as sponsor for this study.

Permission is based on the NHS REC favourable opinion given on 16.12.2014 date and amendment submitted on 18.12.2014.

Please notify us of the date of your first patient first visit. If you experience any problems recruiting, please contact the R&I office for advice and support.

We wish you every success with your study. We are keen to support good research at North Bristol NHS Trust and are pleased that you have decided to conduct your project here.

The lead Research Facilitator for this study is Mary, who will remain your ongoing main point of contact. They can be reached at the following email address: [research@nbt.nhs.uk](mailto:research@nbt.nhs.uk)<<mailto:research@nbt.nhs.uk>>.

Approval is given on the understanding that this project be carried out according to Good Clinical Practice and UK Statutory Instrument, and within the guidelines of the NHS Research Governance Framework for Health and Social Care, and NHS Trust policies, procedures, and SOPs which are available online at <http://www.nbt.nhs.uk/research>.

In particular you have responsibility for:



- Ensuring that, all participants sign informed consent (whenever applicable)
- Adhering to the protocol as agreed by the Research Ethics Committee and ensuring your co-workers do the same.
- Adhering to National Research Ethics Service and other applicable regulatory (e.g. MHRA) reporting requirements.
- Ensuring all recruitment figures are uploaded to the Edge database on a weekly basis.
- Providing us with information about any amendments to the protocol, changes in funding, personnel or end date. Amendments should be submitted in accordance with guidance in IRAS.
- Informing us of any research-related adverse events.
- Ensuring that any staff working on this study at this site have been issued with a contract with NBT (honorary, substantive or bank) or a letter of access before they commence work on the study at this site.
- Maintenance of an Investigator Site File and/or Trial Master Files\*

Researchers who hold substantive or honorary contracts with North Bristol NHS Trust (NBT) will be covered against claims of negligence by patients of NBT under the Clinical Negligence Scheme for Trusts (CNST). This scheme does not cover 'no fault' compensation and the Trust is precluded from taking out separate insurance to cover this. Any patient or volunteer taking part in the study is entitled to know that if they suffered injury as a result of participating in the study they would first have to prove negligence in a court of law before they could gain compensation. If the study involves patients of any other Trust or healthcare organisation, you will need to confirm the indemnity arrangements with that organisation.

In addition, other information may be requested from time to time and lay summary of the results will be requested from you at the end of the study.

This full R&D approval document will need to be filed in your Investigator Site File and/or Trial Master Files.

In accordance with the NBT Research Monitoring and Audit policy, this study is subject to audit by the R&I Office. We will contact the Principal Investigator to make appropriate arrangements for this.

Many thanks,

Dr Nicola Williams  
Deputy Director  
Research & Innovation  
North Bristol NHS Trust

Tel: 0117 323 6468  
Fax: 0117 323 6192  
<http://www.nbt.nhs.uk/research>